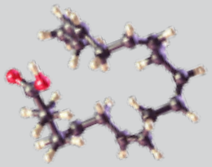
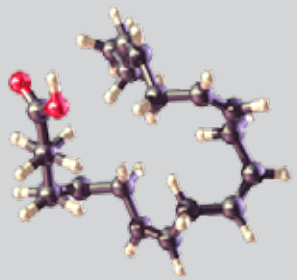
Cancer Nutrition Therapy Clinical Compendium

Welcome to the ***Interactive ProSure® Clinical Trial Compendium.*** Click on the table of contents above to jump to a specific chapter. You can also use the left and right arrows at the bottom right to navigate through the pages.



EPA - eicosapentaenoic acid

Abbott
A Promise for Life



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Introduction

This compendium includes a summary of 29 publications based on 21 clinical studies conducted with ProSure, a therapeutic nutritional product scientifically formulated to address the nutritional needs of people with cancer-induced weight loss or who are at risk for developing this complication. These 21 studies have been conducted in patients with a range of cancer types including: pancreatic, lung, head and neck, colorectal, esophageal, and solid tumors and leukemia in children. A supporting publications section is included in this compendium that includes summaries of clinical studies that support the use of fish oil supplements in patients with cancer. Other papers included in this section are an international consensus definition and classification of cancer cachexia and a minireview paper of studies that evaluated the role of eicosapentaenoic acid on lean body mass in cancer cachexia.

People with cancer often experience weight loss along with a loss of quality of life—conditions that reach far beyond the battle against malignant cell growth. Unintended weight loss is sometimes the first sign of cancer a patient notices, but weight loss is just one aspect of a more complicated condition known as cancer cachexia. Cachexia may also lead to anorexia, anemia, muscle loss, decreased strength, and physical and mental fatigue. Such impairments can in turn lead to malnutrition, social isolation, and depression.

Cancer cachexia has recently been defined by an international consensus panel as a multifactorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. The pathophysiology is characterised by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism. Cancer cachexia is caused by factors that are released by certain tumors and by the host's inflammatory response to the presence of the tumor. These factors depress appetite and impair the body's metabolism of dietary fat, protein, and carbohydrate.

Such changes actually begin before weight loss is evident and can worsen as cancer progresses. Studies have shown that cancer cachexia can be managed in part by specialized nutrition. ProSure is clinically proven to benefit people with cancer. If weight loss due to cancer cachexia is not effectively treated, poor outcomes can result. Such outcomes include decreased response to cancer treatments, increased frequency of complications and infections, and shortened survival. In addition to survival, people with cancer are particularly concerned about restoring and maintaining quality of life.

Clinical studies demonstrate that drinking ProSure daily as part of an overall cancer care plan:

- Promotes weight gain
- Helps build or maintain lean body mass
- Improves physical activity
- Improves quality of life
- Increases strength
- Improves appetite and dietary intake
- Attenuates the proinflammatory response

ProSure is enriched with eicosapentaenoic acid (EPA), which helps decrease the harmful metabolic changes induced by tumor-related factors. Calorically dense with a high amount of protein, ProSure helps build lean body mass. ProSure's unique combination of EPA with protein- and energy-rich ingredients helps counter the physiological abnormalities that underlie weight loss due to cancer cachexia. For cancer patients, ProSure is recommended as two 240-mL servings per day along with regular food consumption. Studies have shown that adding ProSure to the diet does not inhibit usual meal intake but actually improves appetite so that meal intake improves.

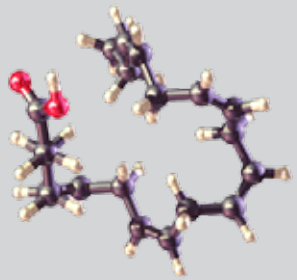
Cover

Introduction

ProSure Clinical Studies

Supporting Publications

This is a navigatable book shelf. Click on the books to view each ProSure® publication.



EPA - eicosapentaenoic acid

The effect of an oral nutritional supplement enriched with fish oil on weight-loss in patients with pancreatic cancer

Barber MD, Ross JA, Voss AC, Tisdale MJ, Fearon KCH ***Br J Cancer. 1999;81:80-86***

In a prospective, single-arm, pilot study conducted by Barber and colleagues, ProSure was given to weight-losing patients with advanced pancreatic cancer who had a median weight loss of 2.9 kg/month (6.4 lb/month) before enrollment. Weight, body composition, and functional status data were collected at baseline, 3 weeks, and 7 weeks. Resting energy expenditure (REE), food intake, and quality of life (QoL) data were collected at baseline and 3 weeks only.

Objective

To assess whether the provision of additional calories and protein in conjunction with fish oil could reverse weight-loss in patients with advanced pancreatic cancer.

Study Design

- STUDY POPULATION: Pancreatic (n = 20)
- LENGTH OF STUDY: 7 weeks
- INTERVENTION: 2 servings ProSure (240 mL/serving)

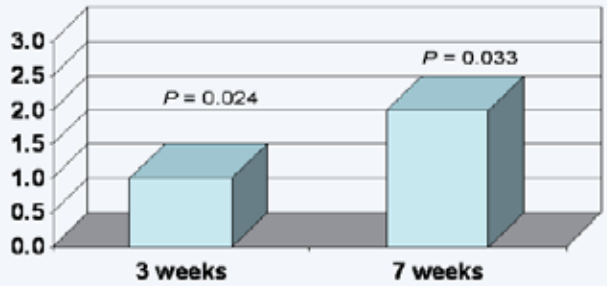
Outcomes

- Median ProSure consumption:1.9 servings/day
- WEIGHT GAIN:
  3 weeks (median 1.0 kg [2.2 lb]) (*P* = 0.024)
  7 weeks (median 2.0 kg [4.4 lb]) (*P* = 0.033)
- **Increased lean body mass. Statistically significant increases in lean body mass at both 3 (median 1.0 kg; *P* = 0.0064) and 7 weeks (1.9 kg; *P* = 0.0047).** Weight gain was predominantly lean body mass (95% of total weight gain), not fat or water.
- **Increased appetite and dietary intake. Statistically significant improvements in appetite (*P* = 0.001) and dietary intake (*P* = 0.0016) at 3 weeks.** Participants consumed a median additional 370 Cal/day at 3 weeks. They did not substitute ProSure for their usual food intake, rather, ProSure supplemented their diet and increased caloric intake.
- **Decreased resting energy expenditure (REE).** Statistically significant reduction in REE or resting metabolic rate (RMR) at 3 weeks.

Study Conclusions

This small pilot study suggests that in contrast to conventional nutritional supplements, a fish-oil enriched supplement may reverse cachexia in patients with advanced pancreatic cancer.

Change in Weight (kg) After Consuming a Fish-oil Enriched Nutritional Supplement



Fish-oil enriched nutritional supplement attenuates progression of the acute-phase response in weight-losing patients with advanced pancreatic cancer

Barber MD, Ross JA, Preston T, Shenkin A, Fearon KCH ***J Nutr. 1999;129:1120-1125***

Weight-losing patients with advanced pancreatic cancer were enrolled in this prospective, single-center, open-label study.

Objective

To evaluate the effect of a fish-oil enriched nutritional supplement on the levels of individual acute-phase proteins in patients with advanced pancreatic cancer.

Study Design

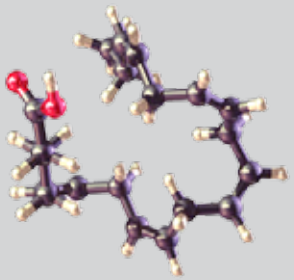
- **STUDY POPULATION**: Pancreatic (n = 36; ProSure 18, Supportive care 18); Healthy controls (n = 6)
- **LENGTH OF STUDY**: 4 weeks
- **INTERVENTION**: 2 servings ProSure (240 mL/serving) or supportive care

Outcomes

- Significant increase in negative acute phase proteins (albumin, prealbumin, and transferrin) (+1.32 g/L) in patients receiving the fish-oil enriched nutritional supplement (P = 0.048) compared with a significant decrease (-2.44 g/L) in the patients receiving supportive care. The difference between the two groups was highly significant (P = 0.0012)
- Although not a primary outcome, a positive effect on weight was observed after 4 weeks in the patients receiving the fish-oil enriched nutritional supplement (median change in weight = +1.0 kg) compared to the patients receiving supportive care (median change in weight = -2.8 kg)

Study Conclusions

Results from this study suggest that many positive and negative acute-phase proteins are altered in patients with advanced pancreatic cancer. Consuming a fish-oil enriched nutritional supplement may help stabilize the acute-phase protein response which may play a role in reducing wasting in patients with advanced pancreatic cancer.



EPA - eicosapentaenoic acid

Metabolic response to feeding in weight-losing pancreatic cancer patients and its modulation by a fish-oil enriched nutritional supplement

Barber MD, McMillan DC, Preston T, Ross JA, Fearon KCH ***Clin Sci. 2000;98:389-399***

Barber and colleagues enrolled weight-losing, non-diabetic patients with unresectable pancreatic adenocarcinoma and healthy, weight stable controls in this prospective, single-center, single-arm study. Patients with cancer had a rate of weight loss of 2.9 kg/month prior to enrollment. Resting energy expenditure was measured in the fasting and fed state using indirect calorimetry. Bioimpedence analysis was used to estimate body composition.

Objective

To evaluate the metabolic response to feeding in patients with cancer cachexia compared with healthy controls and to determine the effect on the metabolic response to feeding after consuming a fish-oil enriched nutritional supplement for 3 weeks in patients with advanced pancreatic cancer.

Study Design

- **STUDY POPULATION:** Pancreatic (n = 16); Healthy weight-stable controls (n = 6)
- **LENGTH OF STUDY:** 3 weeks
- **INTERVENTION:** 2 servings ProSure (240 mL/serving)

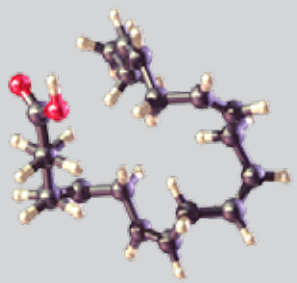
Outcomes

After 3 weeks of consuming a median 1.9 cans/day (range 1.25-2.0) of the fish-oil enriched nutritional supplement, patients experienced:

- Median weight gain of 1.0 kg (-0.25 to 1.75) ($P < 0.05$ compared with baseline)
- Median increase in lean body mass of 0.75 kg (0.1-1.6) ($P < 0.05$)
- No effect on fat mass, 0.0 kg (-0.6 to 0.9)
- Resting energy expenditure rose significantly in response to feeding (9.6%) and was no different from baseline healthy control values.

Study Conclusions

Results suggest that normalization of the metabolic response can be achieved in both the fasted and fed state in weight-losing patients consuming a fish-oil enriched nutritional supplement. Nutritional status also improved.



EPA - eicosapentaenoic acid

Effect of a fish-oil enriched nutritional supplement on metabolic mediators in patients with pancreatic cancer cachexia

Barber MD, Fearon KCH, Tisdale MJ, McMillan DC, Ross JA ***Nutr Cancer. 2001;40(2):118-124***

Barber and colleagues enrolled weight-losing patients with pancreatic cancer in this prospective, single-arm study. Patients had a rate of weight loss of 2.9 kg/month prior to enrollment.

Objective

To evaluate the effects of a fish-oil enriched nutritional supplement on cytokine and hormonal mediators thought to play a role in cancer cachexia.

Study Design

- **STUDY POPULATION:** Pancreatic (n = 20)
- **LENGTH OF STUDY:** 3 weeks
- **INTERVENTION:** 2 servings ProSure (240 mL/serving)

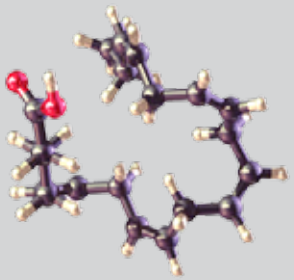
Outcomes

After 3 weeks of consuming a median 1.9 cans/day (range 1.25-2.0) of the fish-oil enriched nutritional supplement, patients experienced:

- **Significant decrease in IL-6** from a median of 16.5 to 13.7 ng/mL; *P* = 0.015
- **Significant increase in serum insulin concentration** from a median of 3.3 to 5.0 mU/L; *P* = 0.0064
- **Significant decrease in the cortisol-to-insulin ratio** (*P* = 0.0084)
- **Significant decrease in the percent of patients excreting proteolysis inducing factor** from 88% to 40%; *P* = 0.008
- Median weight gain of 1.0 kg (interquartile range -0.1 to +2.0, *P* = 0.024 versus baseline)

Study Conclusions

Results of this study demonstrate that a number of catabolic mediators of cachexia can be modulated by a fish-oil enriched nutritional supplement in patients with pancreatic cancer. The modulation of these catabolic mediators may explain the reversal of weight loss observed in the patients consuming this supplement.



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Weight gain is associated with improved quality of life in patients with cancer cachexia consuming an energy and protein dense, high n-3 fatty acid oral supplement

von Meyenfeldt M, Ferguson M, Voss A, Fearon K, Moses A, van Geenen R, Gouma DJ, Roy A, Giacosa A, van Gossum A, Tisdale M
Proc Am Soc Clin Oncol. 2002;21:385A

In a multicenter, randomized, double-blind, controlled trial, cachectic patients with pancreatic cancer were randomized to consume two servings of an energy and protein dense oral supplement enriched with n-3 fatty acids or an isocaloric, isonitrogenous control. Body weight, quality of life, and grip strength were measured at baseline and after 8 weeks.

Objective

To evaluate the effect of an energy and protein dense oral supplement enriched with n-3 fatty acids (ProSure) on body weight and quality of life in cachectic patients with pancreatic cancer.

Study Design

- **STUDY POPULATION**: Pancreatic (n = 200; ProSure = 95, control = 105)
- **LENGTH OF STUDY**: 8 weeks
- **INTERVENTION**: 2 servings/day ProSure (240 mL/serving) or isocaloric, isonitrogenous control

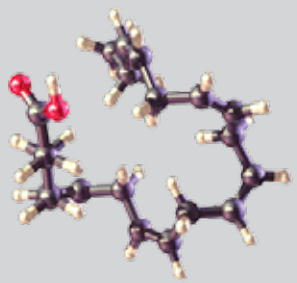
Outcomes

Compared to the control group, weight change in the ProSure group correlated significantly with changes in:

- EQ-5D$_{index}$, (r = 0.46, *P* = 0.001)
- EQ-5D$_{vas}$, (r = 0.38, *P* = 0.01)
- Physical functioning domain of QLQ-C30 (r = 0.33, *P* = 0.022)
- **Grip strength** (r = 0.38, *P* = 0.009)

Study Conclusions

In patients with advanced pancreatic cancer taking ProSure, weight gain was associated with improvements in quality of life and grip strength.



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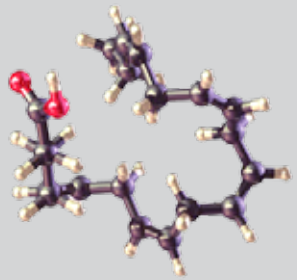


EPA - eicosapentaenoic acid

Effect of a protein and energy dense n-3 fatty acid enriched oral supplement on loss of weight and lean tissue in cancer cachexia: a randomised double blind trial

Fearon KCH, von Meyenfeldt MF, Moses AGW, van Geenen R, Roy A, Gouma DJ, Giacosa A, van Gossum A, Bauer J, Barber MD, Aaronson NK, Voss AC, Tisdale MJ ***Gut. 2003;52:1479-1486***

In a multicenter, randomized, double-blind, controlled trial, 200 cachectic patients with pancreatic cancer were randomized to consume two servings of a protein and energy dense oral supplement enriched with n-3 fatty acids or an isocaloric, isonitrogenous control. Before the study, participants were losing weight at a median rate of 3.3 kg/month (7.3 lb/month). Weight, lean body mass, dietary intake, and quality of life (EORTC QLQ-C30 and EQ-5D) were measured at baseline and after 8 weeks.

Objective

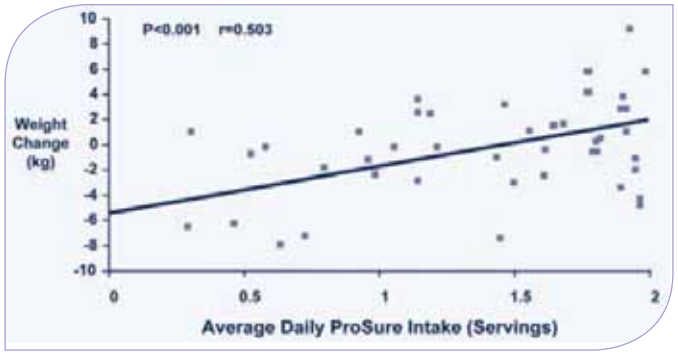
To examine the effect of a high-protein, calorically- dense, EPA-containing nutrition supplement on weight, lean body mass (LBM), dietary intake, and quality of life in cachectic patients with advanced pancreatic cancer.

Study Design

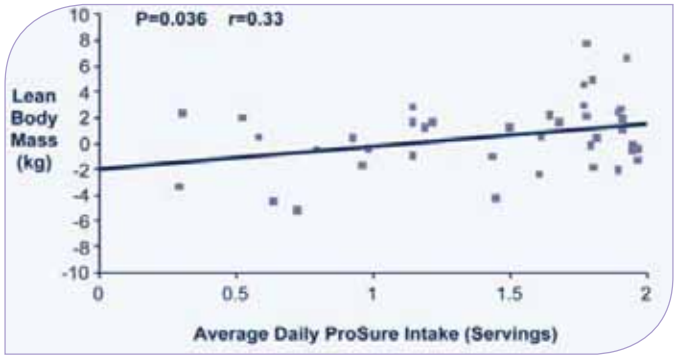
- **STUDY POPULATION**: Pancreatic (n = 200; ProSure = 95, control = 105)
- **LENGTH OF STUDY**: 8 weeks
- **INTERVENTION**: 2 servings/day ProSure (240 mL/serving) or isocaloric, isonitrogenous control

Outcomes

- **Weight**. Weight of people in both groups stabilized at 4 and 8 weeks. **Increased daily intake of ProSure was positively correlated with increased body weight at 8 weeks**. (*P* < 0.001, r = 0.50)



- **Lean body mass**. Increased daily intake of ProSure was positively correlated with **increased lean body mass** at 8 weeks. (r = 0.33, *P* = 0.036). No such correlation was observed in the control group.



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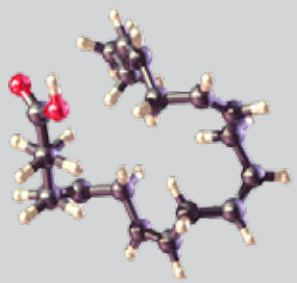

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Effect of a protein and energy dense n-3 fatty acid enriched oral supplement on loss of weight and lean tissue in cancer cachexia: a randomised double blind trial (continued)

Fearon KCH, von Meyenfeldt MF, Moses AGW, van Geenen R, Roy A, Gouma DJ, Giacosa A, van Gossum A, Bauer J, Barber MD, Aaronson NK, Voss AC, Tisdale MJ ***Gut. 2003;52:1479-1486***

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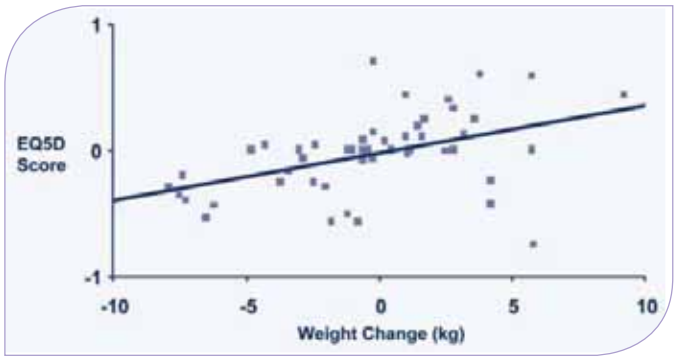
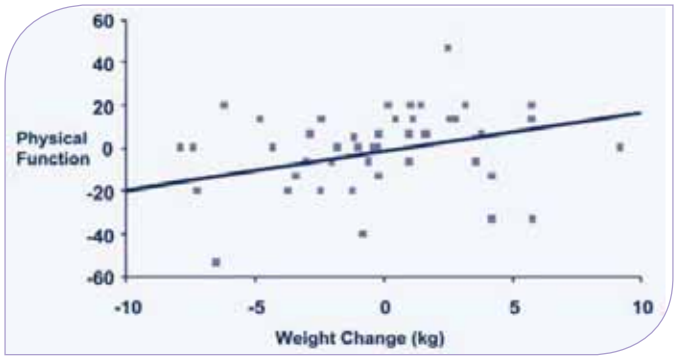
- **Dietary intake**. People consuming ProSure had a significant **increase in total (meal plus supplement) energy and protein intake (*P* ≤ 0.001).** There was no increase in the control group.
- **Quality of life (QOL) and grip strength**. ProSure intake positively correlated with QOL measured by the EQ-5D $_{index}$ (r = 0.37, *P* = 0.01), but there was no correlation in the control group. **Weight gain** in the ProSure group also **correlated with improvements in other measures of QOL and with measures of physical function:** EQ-5D$_{index}$ (r = 0.46, *P* = 0.001), EQ-5D$_{vas}$ (r = 0.38, *P* = 0.01), physical functioning domain of QLQ-C30 (r = 0.33, *P* = 0.022), and grip strength (r = 0.38, *P* = 0.009). There was no correlation in the control group.

Effect of weight change on EQ5D Score

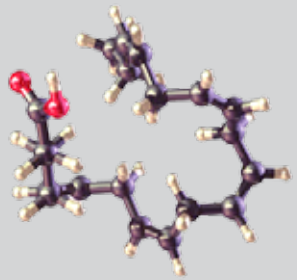


Effect of weight change on QOL-C30 physical function score



Study Conclusions

Supplement intake in both groups was below the recommended 2 servings/day (average 1.4 servings/day). Therefore, a post-hoc dose response analysis was undertaken and revealed that when the supplements were taken at the recommended dose, only the patients consuming the n-3 fatty acid enriched energy and protein dense oral supplement experienced net gain of weight, lean tissue, and improved quality of life.



EPA - eicosapentaenoic acid

Reduced total energy expenditure and physical activity in cachectic patients with pancreatic cancer can be modulated by energy and protein dense oral supplement enriched with n-3 fatty acids

Moses AWG, Slater C, Preston T, Barber MD, Fearon KCH ***Br J Cancer. 2004;90:996-1002***

In a prospective, randomized, double-blind, controlled trial, Moses and colleagues evaluated the effect of ProSure on physical activity level (PAL) in 19 weight-losing patients with pancreatic cancer. Study participants were asked to consume 2 cans/day of either an n-3 fatty acid containing oral nutritional supplement or an isocaloric, isonitrogenous control for 8 weeks. Total energy expenditure (TEE) was measured at baseline (within the first 14 days of the study) and again between 6 and 8 weeks using the doubly-labeled water technique. Resting energy expenditure (REE) was measured by indirect calorimetry, and PAL was calculated by the formula PAL = TEE/REE.

Objective

To assess the total energy expenditure (TEE), resting energy expenditure (REE) and physical activity level (PAL) in cachectic patients with advanced pancreatic cancer.

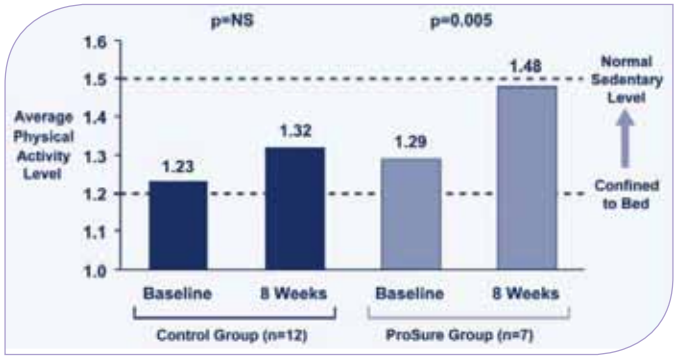
Study Design

- **STUDY POPULATION:** Pancreatic (n = 19; ProSure = 7, control = 12)
- **LENGTH OF STUDY**: 8 weeks
- **INTERVENTION**: 2 servings/day ProSure (240 mL/serving) or isocaloric, isonitrogenous control

Outcomes

- **Physical Activity Level (PAL)**. There was a statistically significant (*P* = 0.005) increase from baseline PAL in the ProSure group. There was no significant PAL change in the control group; most patients remained confined to bed. This significant increase in PAL parallels the significantly increased Karnofsky Performance Status previously reported for pancreatic cancer patients who received ProSure nutrition. (Barber, et al. *Br J Cancer*. 1999).

Change in PAL for patients treated with ProSure versus control*



*Moses AG, Slater C, Barber MD, Fearon KC, Preston T. An experimental nutrition supplement enriched with n-3 fatty acids and antioxidants is associated with an increased physical activity level in patients with pancreatic cancer cachexia. *Clin Nutr*. 2001;20 (Suppl 3):21.

Study Conclusions

Patients with pancreatic cancer consuming ProSure experienced an increase in PAL; improving from a baseline PAL of 1.2-1.3 (confined to bed) to a near-normal sedentary level (PAL = 1.5).

Weight stabilisation is associated with improved survival duration and quality of life in unresectable pancreatic cancer

Davidson W, Ash S, Capra S, Bauer J ***Clin Nutr. 2004;23:239-247***

Davidson and colleagues performed a post hoc analysis of data from 107 patients who were enrolled in the Fearon 2003 trial. Patients were included in the post hoc analysis if weight data was available for both baseline and week 8.

Objective

To examine whether weight stabilization was associated with improved survival and QoL and to identify determinants of weight stabilization.

Study Design

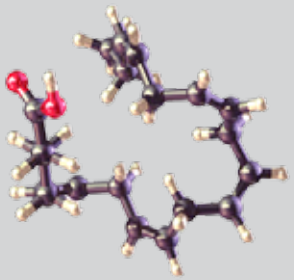
- **STUDY POPULATION:** Pancreatic (n = 107)
- **LENGTH OF STUDY**: 8 weeks
- **INTERVENTION**: 2 servings/day ProSure (240 mL/serving) or isocaloric, isonitrogenous control

Outcomes

- Patients with weight stabilization survived longer from baseline (log rank test 5.53, $P = 0.019$). They also reported higher QoL scores ($P = 0.037$) and a greater mean energy intake ($P < 0.001$) at week 8 than those who continued to lose weight.

Study Conclusions

Weight stabilization over an 8 week period in weight-losing patients with unresectable pancreatic cancer was associated with improved survival duration and QoL.



EPA - eicosapentaenoic acid

EPA enriched nutritional support and fast track surgery for elective periampullary carcinoma

Çoker A, Gurcu B, Uguz A, Hopanci Bicakli D, Tekesin O, Goker E ***Clin Nutr Suppl. 2010;5(2):20***

Patients undergoing elective surgery for periampullary carcinoma were enrolled in this prospective, single-center, open-label study.

Objective:

To evaluate the role of early enteral feeding and an EPA enriched diet during the postoperative period in patients with periampullary carcinoma.

Study Design:

- **STUDY POPULATION**: Patients undergoing elective surgery for periampullary carcinoma (n = 228; fast track rehabilitation after surgery with EPA enriched supplement (ProSure) n = 128; conventional treatment postoperatively n = 100)
- **LENGTH OF STUDY**: 2 months
- **INTERVENTION**: ProSure or conventional treatment

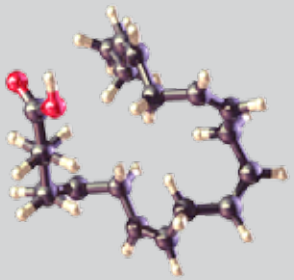
Outcomes:

Fast track treated patients experienced:

- Significantly faster resumption of bowel function (4.1 ± 0.3 days vs 6.3 ± 0.7 days)
- Significantly shorter postoperative hospital length of stay (6.7 ± 0.8 days vs 13.1 ± 0.5 days)
- Less postoperative weight loss at 2 months (6.5% vs 13.6%)

Study Conclusions

Fast track surgery can benefit high-risk patients undergoing elective surgery for periampullary cancer.



EPA - eicosapentaenoic acid

EPA-enriched oral nutritional support in patients with lung cancer: effects on nutritional status and quality of life

Guarcello M, Riso S, Buosi R, D'Andrea F ***Nutr Ther & Metab. 2007;25:25-30***

Guarcello and colleagues evaluated weight losing patients with lung cancer who were scheduled to undergo chemotherapy in a prospective, randomized, blinded, controlled study. Patients were included in the study if they had experienced > 10% body weight loss in the previous 6 months.

Objective:

To evaluate the influence of an EPA-enriched, energy-dense oral supplement on inflammatory and nutritional status, as well as on the quality of life of lung cancer patients.

Study Design:

- **STUDY POPULATION**: Patients with lung cancer eligible for chemotherapy (n = 46; ProSure n = 26, control n = 20)
- **LENGTH OF STUDY**: 60 days
- **INTERVENTION**: 2 servings ProSure (240 mL/serving) or isocaloric, isonitrogenous control

Outcomes:

- Over the 2-month study interval when chemotherapy was administered, only patients who received ProSure showed significant increases in body weight (at 30 days, + 0.9 kg, $P < 0.05$), energy and protein intakes, appetite, and quality of life. In addition, levels of markers for nutritional status were significantly increased at 30 days (prealbumin + 3, $P < 0.05$; transferrin + 26, $P < 0.05$), while levels of inflammatory marker C-reactive protein were decreased in patients who consumed ProSure.

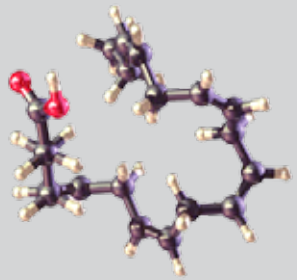
	EPA-ONS (n=26)			Control (n=20)		
	Baseline	30 days	60 days	Baseline	30 days	60 days
Body weight, kg	57.7	58.6*	58.6*	59.1	57	59.1
Functional QOL EORTC QLQ-C30 FS†	64.4	82.2*	77.7*	62.2	72.4	72.2

*$P < 0.05$ vs baseline (Wilcoxon Test)

†EORTC-QLQ-C30 FS, a self-administered, 30-item, quality of life questionnaire measuring physical functioning

Study Conclusions:

Intake of ProSure seems effective in improving the quality of life and nutritional status of patients with lung cancer undergoing chemotherapy without decreasing meal intake.



EPA - eicosapentaenoic acid

A double blind randomized controlled trial on oral nutritional supplementation of omega-3 fatty acids in non-small cell lung carcinoma

van der Meij BS, Languis JA, van Adrichem V, Spreeuwenberg MD, Smit EF, van Leeuwen PA ***Clin Nutr. 2008;3:111 (P193b)***

van der Meij and colleagues conducted a double-blind, randomized, placebo-controlled trial in patients with stage III non-small cell lung carcinoma who were randomized to receive either ProSure or a control supplement during 5 weeks of chemo-radiotherapy.

Objective

To assess the effect of an oral nutritional supplement enriched with omega-3 fatty acids on nutritional status in patients with non-small cell lung carcinoma receiving chemo-radiotherapy.

Study Design

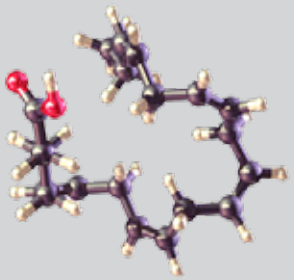
- **STUDY POPULATION:** Patients with stage III non-small cell lung carcinoma receiving chemo-radiotherapy (n = 40; ProSure = 20, control = 20)
- **LENGTH OF STUDY:** 5 weeks
- **INTERVENTION:** 2 servings ProSure (240 mL/ serving) or isocaloric isonitrogenous control

Outcomes

- Compared to the control group, the ProSure group had **better weight maintenance** during weeks 1, 2, and 4 (1.2 kg, 1.4 kg, and 1.8 kg, ***P* < 0.05)** and **higher EORTC- QLQC30 physical function scores at week 5 (*P* < 0.05).**

Study Conclusions

Results of this study underscore the beneficial effects of a high-protein, calorically-dense, low-fat nutritional supplement enriched with EPA (ProSure) on nutritional status and physical function in patients with non-small cell lung carcinoma undergoing chemo-radiotherapy.



EPA - eicosapentaenoic acid

Supplemental drinks enriched with omega-3 fatty acids improve nutritional status and quality of life in lung cancer patients

van der Meij BS, Languis JA, Zadelaar SM, Spreeuwenberg MD, von Blomberg ME, Paul MA, Smit EF, van Leeuwen PA
JPEN J Parenter Enteral Nutr. 2009;33:207

van der Meij and colleagues conducted a double-blind, randomized, placebo-controlled trial in patients with stage III non-small cell lung carcinoma who were randomized to receive either ProSure or a control supplement during 5 weeks of chemo-radiotherapy.

Objective

To compare the effects on nutritional status, quality of life, physical activity and immune parameters of a supplemental drink enriched with omega-3 fatty acids with a placebo supplemental drink in patients with non-small cell lung cancer receiving chemo-radiotherapy.

Study Design

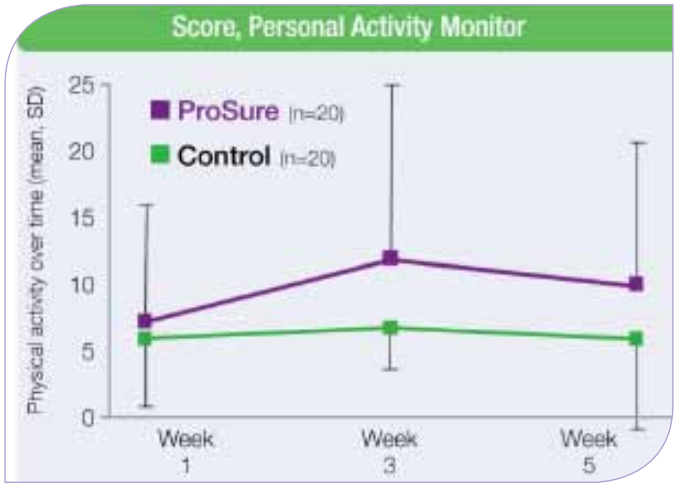
- **STUDY POPULATION:** Patients with stage III non-small cell lung carcinoma receiving chemo-radiotherapy (n = 40; ProSure = 20, control = 20)
- **LENGTH OF STUDY:** 5 weeks
- **INTERVENTION:** 2 servings ProSure (240 mL/ serving) or isocaloric isonitrogenous control

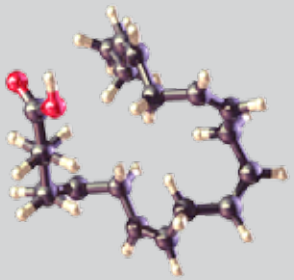
Outcomes

- Compared to the control group, the ProSure group had **better weight maintenance** during weeks 1 2, and 4 (1.1 kg, 1.4 kg, and 1.7 kg, ***P* < 0.05) and higher physical functioning as measured by EORTC-QLQ-C30 and physical activity measured by wearing the Personal Activity Monitor at weeks 3 and 5 (*P* < 0.05).**

Study Conclusions

Results of this study suggest beneficial effects of a high-protein, calorically-dense, low-fat nutritional supplement enriched with EPA (ProSure) on nutritional status, physical activity and quality of life, but not on immune parameters in patients with non-small cell lung carcinoma undergoing chemo-radiotherapy.





EPA - eicosapentaenoic acid

Oral nutritional supplements containing (n-3) polyunsaturated fatty acids affect the nutritional status of patients with stage III non-small cell lung cancer during multimodality treatment

van der Meij BS, Langius JAE, Smit EF, Spreeuwenberg MD, von Blomberg BME, Heijboer AC, Paul MA, van Leeuwen PAM

J Nutr. 2010;140:1774-1780

van der Meij and colleagues conducted a double-blind, randomized, placebo-controlled trial in patients with stage III non-small cell lung carcinoma.

Objective:

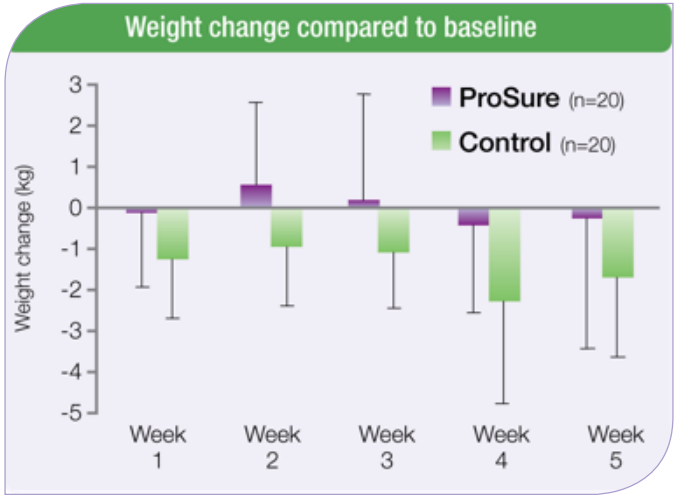
To assess the effects of an oral nutritional supplement containing n-3 fatty acids on nutritional status and inflammatory markers in patients with non-small cell lung cancer undergoing multimodality treatment.

Study Design:

- **STUDY POPULATION**: Patients with stage III non-small cell lung carcinoma receiving chemo-radiotherapy (n = 40; ProSure n = 20, control n = 20)
- **LENGTH OF STUDY**: 5 weeks
- **INTERVENTION**: 2 servings ProSure (240 mL/serving) or isocaloric control

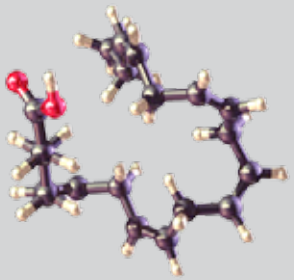
Outcomes:

- Compared to the control group, the ProSure group had:
  - Better weight maintenance after weeks 2 and 4 (1.3 kg and 1.7 kg, respectively, $P < 0.05$)
  - Better fat free mass maintenance after 3 and 5 weeks (1.5 and 1.9 kg, respectively, $P < 0.05$)
  - A trend towards a lower IL-6 production after 5 weeks (-27.9; $P = 0.08$)



Study Conclusions:

Results of this study underscore the beneficial effects of a protein and energy-dense, oral nutritional supplement containing n-3 fatty acids on nutritional status in patients with stage III non-small cell lung carcinoma undergoing multimodality treatment.



EPA - eicosapentaenoic acid

Influence of nutritional parameters including bioelectrical impedance and systemic inflammatory response on quality of life and prognosis in advanced non-small cell lung cancer patients naive to chemotherapy: a prospective study

Sánchez-Lara K, Turcott JG, Juárez E, Guevara P, Nuñez-Valencia C, Flores D, Oñate-Ocaña, LF, Arrieta O

Presented in part as a poster at the 14th World Conference on Lung Cancer of the International Association for the Study of Lung Cancer, July 3-7, 2011, Amsterdam, The Netherlands

Patients with advanced non-small cell lung cancer (NSCLC) who were naive to treatment with good performance status (ECOG 0-2) were included in this prospective, randomized, single-blind study.

Objective:

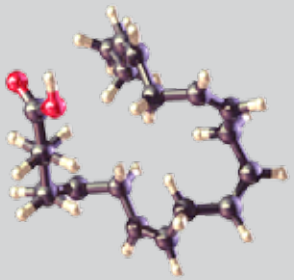
To evaluate the influence of nutritional parameters on quality life and survival in advanced NSCLC patients.

Study Design:

- **STUDY POPULATION**: Patients with advanced NSCLC, n =119
- **LENGTH OF STUDY**: One week before treatment through completion of two courses of chemotherapy ~ 2 months
- **INTERVENTION**: 2 servings ProSure (240 mL/serving) or isocaloric diet with nutritional assessment

Outcomes:

- Malnutrition measured by Subjective Global Assessment (SGA), weight loss >10%, body mass index (BMI) >24 was associated with a decrease in the majority of quality of life (QoL) domains.
- Patients with ECOG 2 and malnutrition parameters showed lower overall survival (OS); however after multivariate analysis, ECOG 2 (HR 2.7 [95% CI 1.5-4.7] *P* =0.001), phase angle ≤ 5.8 (3.02 [1.2-7.11] *P* =0.011) and SGA (2.7 [95% CI 1.31-5.5] *P* =0.005) were associated with poor survival.
- Patients were divided into low, medium, and high risk groups according to regression coefficients with OS at 1 year of 78.4%, 53% and 13.8%, respectively.



EPA - eicosapentaenoic acid

The effect of an oral nutritional supplement with eicosapentaenoic acid on body composition, energy intake, quality of life, toxicity and survival in advanced non-small lung cancer

Sánchez-Lara K, Turcott JG, Juárez E, Guevara P, Villanueva G, Arrieta O ***Presented in part as a poster at the 2011 European Multidisciplinary Cancer Congress September 26th in Stockholm, Sweden***

Patients with advanced non-small cell lung cancer (NSCLC) who were naive to treatment were included in this prospective, randomized, study.

Objective:

To evaluate the effect of an EPA-containing supplement on body composition, quality of life, and survival in patients with advanced NSCLC.

Study Design:

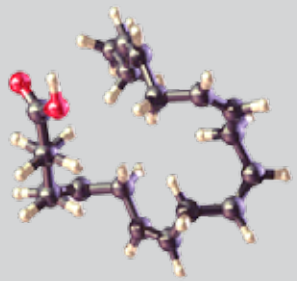
- **STUDY POPULATION**: Patients with advanced NSCLC, n = 92
- **LENGTH OF STUDY**: Two courses of chemotherapy
- **INTERVENTION**: 2 servings ProSure (240 mL/serving) or isocaloric diet

Outcomes:

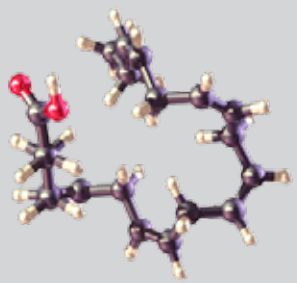
Between baseline and the end of the second cycle of chemotherapy, patients who consumed the EPA-containing supplement had **a significant increase** in:

- calories, protein, and carbohydrates (P <0.001) compared with the control group.
- lean body mass (+1.6 kg) despite a slight decrease in weight, (P = 0.04) compared with the control group (-0.3 kg).

In addition, the patients who consumed the EPA-containing supplement also experienced an improvement in global and physical measures of quality of life with less fatigue, anorexia, and neuropathy compared with the control group.



EPA - eicosapentaenoic acid



EPA - eicosapentaenoic acid

A randomized clinical trial with oral immunonutrition (ω3-enhanced formula vs arginine-enhanced formula) in ambulatory head and neck cancer patients

de Luis DA, Izaola O, Aller R, Cuellar L, Terroba MC ***Ann Nutr Metab. 2005;49:95-99***

In a prospective, randomized, controlled, blinded study by de Luis and colleagues, patients with head and neck cancers were randomized to receive either 2 servings a day of a nutritional supplement (ProSure) or an isocaloric, arginine-enriched drink during a 12-week period of recovery from cancer surgery.

Objective

To investigate whether oral ambulatory nutrition of head and neck cancer patients, using an ω3 fatty acid-enhanced diet (low ratio ω6/ω3 fatty acids) versus an arginine-enhanced diet, could improve nutritional variables as well as clinical outcome, postoperative infections, and wound complications.

Study Design

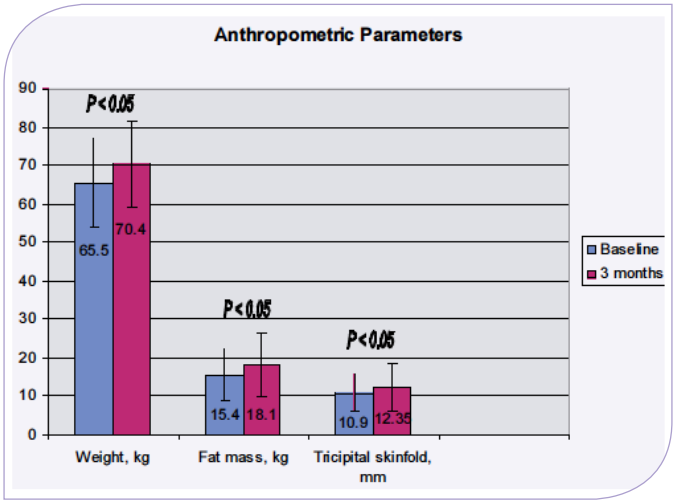
- **STUDY POPULATION:** Post-surgical head and neck cancer patients (n = 73; ProSure = 38, arginine-enhanced supplement = 35)
- **LENGTH OF STUDY:** 12 weeks
- **INTERVENTION:** 2 servings ProSure (240 mL/serving) or 2 servings (300 mL/serving) arginine-enhanced supplement

Outcomes

- From baseline to 3 months, patients consuming ProSure exhibited a statistically significant increase in weight (65.5 ± 11.5 kg vs 70.4 ± 11.1 kg; $P < 0.05$), fat mass (15.4 ± 6.6 vs 18.1 ± 8.4 kg; $P < 0.05$), and tricipital skinfold (10.9 ± 4.7 vs 12.35 ± 6.1 mm; $P < 0.05$).

Study Conclusions

Use of ProSure significantly increased weight gain, including both body fat and visceral proteins. The arginine-enriched drink increased only visceral protein.



Effect of oral supplementation enriched with omega-3 fatty acids in inflammatory parameters and oxidative stress in patients with otolaryngologist cancer treated with radiotherapy

Garcia-Almeida JM, Murri-Pierri M, Lupiáñez-Pérez Y, Rico-Pérez JM, Saracho-dominguez H, Roca MM, Garcia-Aleman J, Casado-Fernández G, Medina-Carmona J, Tinahones-Madueño F ***Clin Nutr Suppl. 2010;5(2):140***

Patients with otolaryngeal cancer who were undergoing radical radiotherapy were enrolled in this prospective, single-center, open-label study.

Objective:

To evaluate the effect of oral supplementation enriched with omega-3 fatty acids on inflammatory parameters and oxidative stress in patients with otolaryngeal cancer treated with radiotherapy.

Study Design:

- **STUDY POPULATION:** Patients with otolaryngeal cancer (n = 32; omega-3 fatty acids enriched supplement (ProSure) n = 16, control n = 16)
- **LENGTH OF STUDY:** During radiotherapy and 3 months after treatment
- **INTERVENTION:** ProSure or standard supplement

Outcomes:

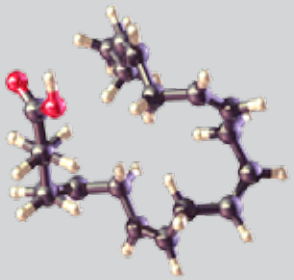
Oxidative stress and inflammatory parameters were significantly better in the patients supplemented with omega-3 fatty acids compared to the patients who received the standard supplement.

After 3 months of treatment, the patients supplemented with omega-3 fatty acids experienced:

- An increase in total antioxidant capacity ($P < 0.05$)
- An increase in glutathione peroxidase activity ($P < 0.01$)
- A decrease in lipoperoxide levels ($P < 0.05$)
- A decrease in C-reactive protein levels ($P < 0.05$)

Study Conclusions:

Supplementation with omega-3 fatty acids appears to improve oxidative stress in patients with otolaryngeal cancer treated with radiotherapy.



EPA - eicosapentaenoic acid

Lean body mass gain in patients with head and neck squamous cell cancer treated perioperatively with a protein- and energy-dense nutritional supplement containing eicosapentaenoic acid

Weed HG, Ferguson ML, Gaff RL, Hustead DS, Nelson, JL, Voss AC ***Head Neck. 2011;33:1027–1033***

Weed and colleagues conducted a prospective, single-arm, open-label study in patients with head and neck cancer experiencing unintentional weight loss of at least 5% during the preceding 6 months who were scheduled for surgical resection with curative intent.

Objective:

To determine the safety and tolerance and the impact of pre- and post-operative consumption of a protein and energy dense nutritional supplement containing omega-3 fatty acid eicosapentaenoic acid (EPA) on weight and body composition in patients with head and neck cancer-related weight loss undergoing treatment with curative intent.

Study Design:

- **STUDY POPULATION:** Patients with head and neck squamous cell cancer (n = 38)
- **LENGTH OF STUDY**: 2 weeks prior to surgery and during hospitalization
- **INTERVENTION**: 2 servings ProSure (240 mL/serving)

Outcomes:

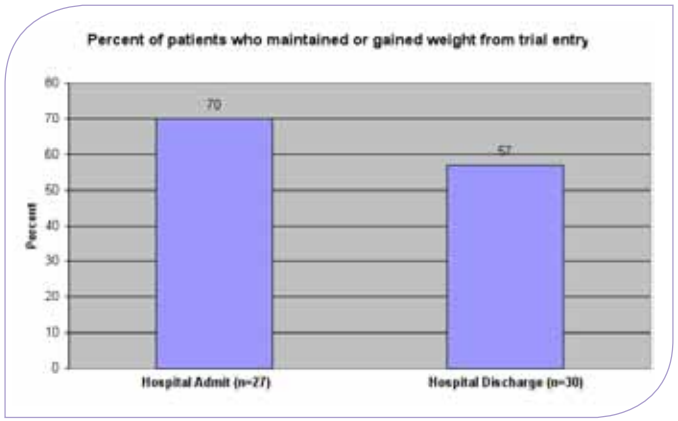
Mean ProSure consumption before surgery was 1.8 cans/day; in-hospital consumption was 1.5 cans/day.

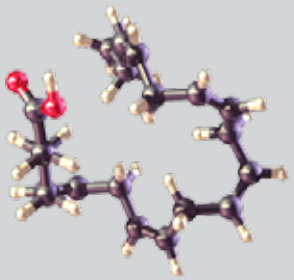
The following changes in weight were noted:

- 70% of patients maintained or gained weight from study entry to time of hospital admission
  - Weight gain from study entry to hospital admission = + 0.71 kg (n = 27)
- 57% of patients maintained or gained weight from study entry to hospital discharge
  - Weight gain from study entry to hospital discharge = + 0.66 kg (n = 30)
- In 23 patients there was a statistically significant increase in mean lean body mass (LBM) from study entry to hospital discharge: +3.20 kg; +7% (*P* < .001).

Study Conclusions:

Data from this pilot study suggests that patients with head and neck cancer can benefit from a protein and energy dense, EPA-containing nutritional supplement before and after surgical treatment.





EPA - eicosapentaenoic acid

The effect of eicosapentaenoic acid in patients with nasopharyngeal cancer receiving concurrent chemoradiotherapy in an outpatient clinic: an open-label prospective randomized trial

Chang JT ***J Clin Oncol. 2011;29 (suppl. Abstr e19550)***

Patients with previously untreated stage IIb-IV nasopharyngeal cancer (NPC) who were to receive concomitant chemoradiotherapy were enrolled in this open-label, prospective, randomized trial.

Objective:

To evaluate the benefit of an EPA-containing nutrition supplement in NPC patients who are receiving concomitant chemoradiotherapy.

Study Design:

- **STUDY POPULATION**: Patients with previously untreated stage IIb-IV NPC (n = 116; EPA-containing nutrition supplement (ProSure) n = 59, control n = 57)
- **LENGTH OF STUDY**: 3 months
- **INTERVENTION**: EPA-containing nutrition supplement or isotonic balanced nutrition formula

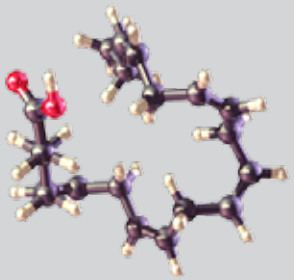
Outcomes:

Significant difference between the groups in infection rates requiring hospitalization:

- 6 patients in the EPA supplement group (10.2%) vs 16 patients in the control group (28.1%), *P* = 0.014

Study Conclusions:

Intake of an EPA-containing supplement was found to decrease the rate of hospital admission due to infection.



EPA - eicosapentaenoic acid

Nutrition intervention using an eicosapentaenoic acid (EPA)-containing supplement in patients with advanced colorectal cancer. Effects on nutritional and inflammatory status: a phase II trial

Read JA, Beale PJ, Volker DH, Smith N, Childs A, Clark SJ ***Support Care Cancer. 2007;15:301-307***

In a prospective, open-label study by Read and colleagues, patients with advanced colorectal cancer were given ProSure 3 weeks before chemotherapy began and for 9 weeks during chemotherapy.

Objective

To assess the impact of an eicosapentaenoic acid-containing protein and energy dense oral nutritional supplement (EPA-ONS) on nutritional and inflammatory status, quality of life (QOL), plasma phospholipids, and cytokine profile, tolerance of irinotecan-containing chemotherapy and EPA-ONS in patients with advanced colorectal cancer receiving chemotherapy.

Study Design

- **STUDY POPULATION:** Patients with colorectal cancer receiving chemotherapy (n = 23) 20 patients completed 3 weeks; and 15 completed 9 weeks
- **LENGTH OF STUDY**: 3-9 weeks
- **INTERVENTION**: 2 servings ProSure (240 mL/ serving)

Outcomes

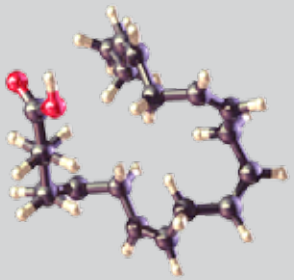
- ProSure feeding (average daily intake 408 mL) produced **a significant increase in mean weight (+2.5 kg, *P* = 0.03) at 3 weeks and preserved lean body mass** during chemotherapy. In addition, there was **a significant increase in energy levels (*P* = 0.03)** during the study, while **quality of life (QOL) was maintained.**

Study Conclusions

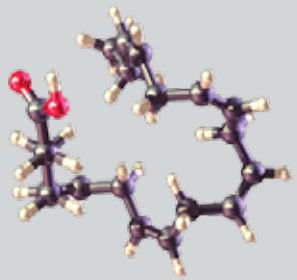
The researchers concluded that ProSure helped patients with advanced colorectal cancer receiving chemotherapy to maintain weight, and lean body mass, and possibly improved symptom control, nutritional status and QOL. Dietary counseling improved compliance with ProSure. Inflammation, measured by C-reactive protein, was stabilized.

Marker	Baseline	Pre-chemo End week 3	During or post-chemo End week 9	*P* value*
Weight, kg	75.9 (17.0)	78.4 (17.5)	78.4 (17.4)	0.03
Lean body mass, kg	50.3 (10.7)	51.4 (10.2)	51.7 (10.6)	NS
C-reactive protein, mg/L	18.2 (13.9)	33.1 (32.6)	19.4 (17.7)	0.004 (end of week 3) 0.02 (end of week 9)
QOL-overall well-being	7 (2.2)	7 (1.7)	8 (1.7)	0.05

Mean values (SD)
**P* values are for baseline vs timepoint value; NS, not significant



EPA - eicosapentaenoic acid



EPA - eicosapentaenoic acid

Enteral nutrition enriched with eicosapentaenoic acid (EPA) preserves lean body mass following esophageal cancer surgery: results of a double-blinded randomized controlled trial

Ryan AM, Reynolds JV, Healy L, Byrne M, Moore J, Brannelly N, McHugh A, McCormack D, Flood P ***Ann Surg. 2009;249:355-363***

In a prospective, randomized, double-blind, controlled trial, Ryan and colleagues studied the effect of consuming an EPA enriched enteral nutrition formula pre- and postoperatively in patients undergoing esophagectomy.

Objective

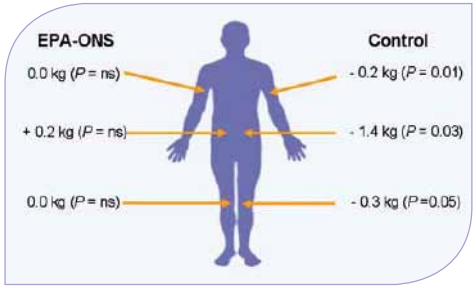
To evaluate the effects of perioperative EPA enriched enteral nutrition on the metabolic, nutritional, and immuno-inflammatory response to esophagectomy, and on postoperative complications.

Study Design

- **STUDY POPULATION**: Patients with resectable esophageal cancer (n = 53; ProSure = 28, control = 25)
- **LENGTH OF STUDY**: 5 days preoperatively (orally) and 21 days postoperatively (jejunostomy)
- **INTERVENTION**: 2 servings ProSure (240 mL/ serving) or isocaloric isonitrogenous control

Outcomes

- ProSure-fed patients **maintained lean body mass** throughout the study, while patients on standard enteral nutrition lost significant amounts of muscle from the leg (0.3 kg ± 0.6; *P* = 0.05), arm (0.17 kg ± 0.3; *P* = 0.01), and trunk (1.44 kg ± 2.7; *P* = 0.03), for a total loss of 1.9 kg (± 3.7) lean body mass. In the hospital, 39% of standard-fed patients experienced severe weight loss (> 5% total body weight), but only 8% of ProSure-fed patients showed such loss, a difference that was statistically significant (*P* = 0.03). Compared with the standard enteral nutrition fed group, the ProSure-fed group also had a significantly (*P* < 0.05) **attenuated stress response to surgery** for **IL-8, IL-10, and TNF-α.**
- In addition, there was no abnormal intra-operative bleeding and no difference between the ProSure group and the control group in prothrombin time, platelets, or $_{D}$-Dimer levels.



Significantly fewer patients fed EPA-ONS (ProSure) experienced severe weight loss in comparison with control-fed patients.

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Enteral nutrition enriched with eicosapentaenoic acid (EPA) preserves lean body mass following esophageal cancer surgery: results of a double-blinded randomized controlled trial (continued)

Ryan AM, Reynolds JV, Healy L, Byrne M, Moore J, Brannelly N, McHugh A, McCormack D, Flood P ***Ann Surg. 2009;249:355-363***

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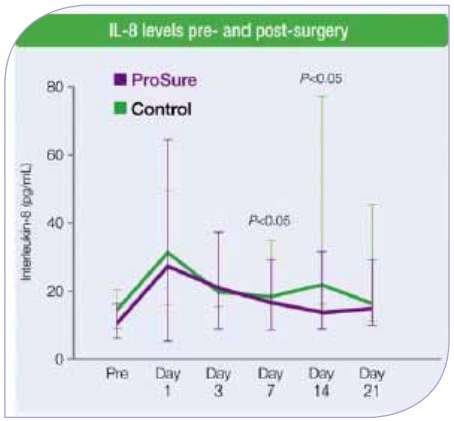
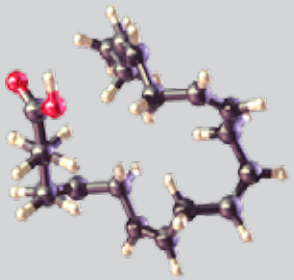


IL-8 levels were significantly lower on postoperative days 7 and 14 in the EPA-containing nutrition group compared to the control nutrition group ($P = 0.05$).

Study Conclusions

The anti-inflammatory and anabolic properties of protein and energy dense EPA-containing nutrition (ProSure) benefit patients undergoing complex, major surgery for esophageal cancer. Such properties may also benefit patients with other solid tumors such as lung and head and neck cancer.



EPA - eicosapentaenoic acid

Complementary effect of ProSure for anticancer chemotherapy

Taniguchi M ***2nd International Conference on Cancer Nutrition Therapy, 2011, Edinburgh, Scotland***

Case study

Objective:

To evaluate the supportive effect of ProSure to anticancer chemotherapy in advanced gastric cancer.

Study Design:

- **STUDY POPULATION**: 60-year-old male post-surgical gastric cancer patient
- **LENGTH OF STUDY**: 7 months
- **INTERVENTION**: 2 servings ProSure (240 mL/serving)

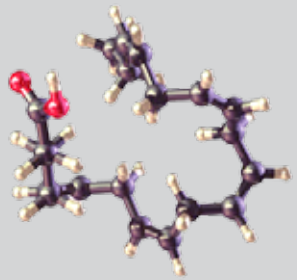
Outcomes:

With oral ProSure supplementation, patient could take foods gradually and was weaned from parenteral nutrition (PN). His body weight and serum albumin level remained stable. Because of his fair nutritional status, chemotherapy could be continued. Serum CEA and CA19-9 levels were decreasing and became normal. He could live at home with normal food intake and oral supplementation of ProSure for seven months post surgery.

Chemotherapy enabled oral supplementation of ProSure (improved stenosis of stomach allowing oral intake), and ProSure enabled continuation of chemotherapy due to improved nutritional status.

Study Conclusions:

ProSure and chemotherapy have complementary effects in a post-surgical patient with advanced gastric cancer.



EPA - eicosapentaenoic acid

Potential usefulness of an EPA-enriched nutritional supplement on cheomotherapy tolerability in cancer patients without overt malnutrition

Trabal J, Leyes P, Forga MT, Maurel J ***Nutr Hosp. 2010;25(5):736-740***

Patients with stage IV colorectal cancer who were going to receive first line chemotherapy were enrolled in this prospective, randomized, controlled, open-label pilot study.

Objective:

To assess the effectiveness of an oral nutritional supplement enriched with eicosapentaenoic acid on chemotherapy tolerability in patients with advanced colorectal cancer. Chemotherapy tolerability was assessed based on variation of changes in health related quality of life (HRQOL).

Study Design:

- **STUDY POPULATION**: Patients with stage IV colorectal cancer (n = 13; EPA enriched supplement (ProSure) n = 6, control n = 7)
- **LENGTH OF STUDY**: 3 months
- **INTERVENTION**: ProSure plus dietary counseling or counseling alone

Outcomes:

At 3 months:

- Patients in the EPA group gained significantly more weight compared to the control group (4.94 kg vs -1.17 kg; *P* = .045).

An overview of HRQOL showed a trend towards improvement in the supplemented group.

After 3 months:

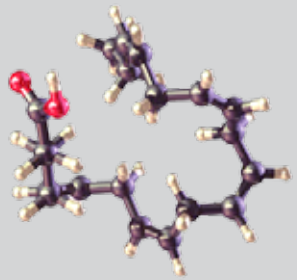
- Statistically significant differences between groups were only found for the Social Function scale (16.67 vs -13.89; *P* = .038).
- Both groups had a decrease in physical function (-4 vs 15.56; *P* = ns); however, only the control had a worsening over 10 points, which is considered clinically meaningful.
- The supplemented group experienced an improvement in role function (13.33 vs 2.78; *P* = ns).
- Changes over 10 points were also found with the control group experiencing more fatigue (-4.44 vs 11.11; *P* = ns) and pain (-10 vs 2.78; *P* = ns).

Chemotherapy compliance:

- No significant differences between groups; however, during the intervention period, none of the 5 patients in the supplemented group experienced a delay or stoppage of their chemotherapy regimen compared to 4 of 6 patients in the control group who experienced some type of interruption in their treatment due to toxicity.

Study Conclusions:

Although this study included a small sample size, results show a positive effect on weight maintenance, and some domains of HRQOL, and chemotherapy tolerability in advanced colorectal cancer patients taking an EPA enriched supplement plus dietary counseling.



EPA - eicosapentaenoic acid

Nutritional support including eicosapentaenoic acid in the prevention of chemoradiotherapy induced acute gastrointestinal complications: a prospective, controlled, clinical evaluation

Kilic D, Pak Y, Oguz M ***3rd National Gastrointestinal Oncology Congress, 2011, Antalya, Turkey***

Well-nourished patients receiving pelvic chemoradiotherapy for rectal cancer were enrolled in this open-label, prospective, controlled trial.

Objective:

To evaluate the efficacy of oral nutritional support with EPA in preventing acute chemoradiotherapy related gastrointestinal complications in patients with rectal cancer.

Study Design:

- **STUDY POPULATION**: Patients with rectal cancer receiving chemoradiotherapy (n = 47; EPA-containing nutrition supplement (ProSure) n = 27, control n = 20)

  Patients received the following chemotherapy regimen: 5FU 425 mg/m^2 and folinic acid 25 mg/m^2 during days 1-4 and 31-33 of radiation treatment. After completion of chemoradiotherapy, patients underwent surgery for total mesorectal excision. After surgery, patients received 4 cycles of chemotherapy containing 5FU 425 mg/m^2 and folinic acid 25 mg/m^2 FA for 5 days for 3 weeks.
- **LENGTH OF STUDY:** duration of radiation
- **INTERVENTION**: 2 servings ProSure (240 mL/serving)

Outcomes:

Patients in the EPA supplement group experienced:

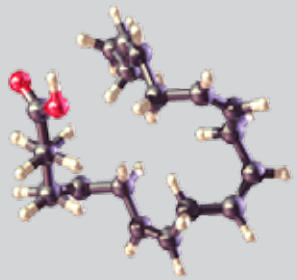
- Less Grade 2 or more diarrhea than the control group, 55% vs 85%, respectively, $P = .038$.
- Less Grade 2 or more GI toxicity than the control group, 40% vs 95%, respectively, $P < .0001$.

When chemoradiotherapy began, all patients were well-nourished. However, at the end of treatment, 5% of the patients in the EPA group and 35% of the controls were found to be malnourished, $P = .044$.

Post treatment quality of life (QOL) scores showed significant differences between the groups in favor of the EPA group for appetite loss, diarrhea, GI symptoms, weight loss, and defecation problems ($P < .05$).

Study Conclusions:

In patients with rectal cancer receiving chemoradiotherapy, use of an oral nutritional supplement with EPA was effective in preventing chemoradiotherapy induced GI complications while maintaining pretreatment QOL.



EPA - eicosapentaenoic acid

Possibility of individualized chemotherapy for patients with advanced recurrent gastric cancer using Glasgow prognostic score (GPS) – an exploratory study on the efficacy of ProSure in cachexia group

Imamura H, Kishimoto T, Kawabata R, Sumida R, Fujii C, Furukawa H ***2nd International Conference on Cancer Nutrition Therapy, 2011, Edinburgh, Scotland***

Patients who started primary chemotherapy for advanced recurrent gastric cancer were enrolled in this open-label trial.

Objective:

To investigate the usefulness of Glasgow prognostic score (GPS) in patients undergoing chemotherapy for gastric cancer and to investigate, in an exploratory manner, the efficacy of ProSure in "cachexia group", i.e., patients with increased CRP level and decreased albumin level.

Study Design:

- **STUDY POPULATION**: Patients with gastric cancer (n = 94)
- **LENGTH OF STUDY**: non-interventional
- **INTERVENTION**: Patients were classified into 4 groups based on CRP level of 0.5 mg/dL and albumin level of 3.5 g/dL

Group A (normal group) normal CRP and normal albumin
Group B (malnutrition group) normal CRP and decreased albumin
Group C (inflammation group) increased CRP and normal albumin
Group D (cachexia group), increased CRP and decreased albumin

Prognosis was compared among the groups.

Additionally, 6 patients in Group D were able to take 240 mL/day or more of ProSure while receiving chemotherapy

Outcomes:

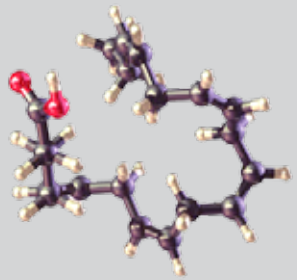
The 94 patients were classified as follows:

Group A, 39 patients (41%)
Group B, 14 patients (15%)
Group C, 14 patients (15%)
Group D, 27 patients (29%)

One-year survival rate was 72% in group A, 63% in group B, 62% in group C, and 36% in group D, demonstrating a significantly poor prognosis in group D ($P = 0.0026$). Of the 6 patients who could take ProSure continuously, 1 improved to group A, and 2 to group B. All three patients who remained in group D showed improvement in CRP or albumin, or both.

Study Conclusions:

GPS is considered a prognostic factor for patients undergoing chemotherapy for gastric cancer. Results suggest that patients in the cachexia group can benefit from taking an EN formula (ProSure) enriched with EPA.



EPA - eicosapentaenoic acid

Nutrition intervention improves outcomes in patients with cancer cachexia receiving chemotherapy—a pilot study

Bauer JD, Capra S ***Support Care Cancer. 2005;13:270-274***

In this prospective, single-arm, pilot study, patients with pancreatic or non-small cell lung cancer received weekly nutritional counseling by a dietitian and were asked to consume a protein- and energy-dense oral nutritional supplement containing EPA (ProSure).

Objective

To examine the effect of nutrition intervention with nutrition counseling by a dietitian and the intake of a protein- and energy-dense oral nutritional supplement containing EPA on outcomes of dietary intake, body composition, nutritional status, functional capacity and quality of life in patients with cancer cachexia receiving chemotherapy.

Study Design

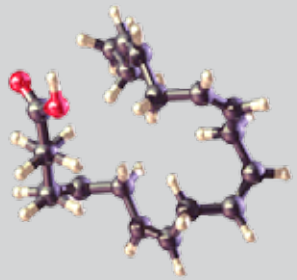
- **STUDY POPULATION**: Patients with pancreatic or non-small cell lung cancer receiving chemotherapy (n = 7)
- **LENGTH OF STUDY**: 8 weeks
- **INTERVENTION**: Weekly nutrition counseling by a dietitian and one can per day of a protein and energy-dense, n-3 fatty acid-enriched oral nutritional supplement between meals.

Outcomes

- Nutritional intervention (weekly counseling and use of ProSure) together with chemotherapy provided significant benefits that included **improvements in quality of life (EORTC QLQ-C30 global scale), performance status (Karnofsky score), mean dietary and energy intake**, as well as clinically significant improvements in weight gain and **increases in lean body mass.**

Study Conclusions

Nutritional intervention (weekly counseling and use of ProSure) for 8 weeks in addition to chemotherapy improved outcomes in patients with pancreatic or non-small cell lung cancer.



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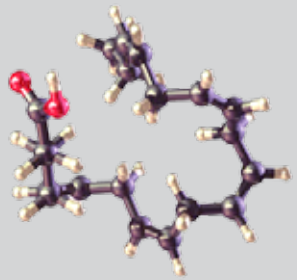


EPA - eicosapentaenoic acid

An eicosapentaenoic acid supplement versus megestrol acetate versus both for patients with cancer-associated wasting: a North Central Cancer Treatment Group and National Cancer Institute of Canada collaborative effort

Jatoi A, Rowland K, Loprinzi CL, Sloan JA, Dakhil SR, MacDonald N, Gagnon B, Novotny, PJ, Mailliard JA, Bushey TIL, Nair S, Christensen B
J Clin Oncol. 2004 Jun 15;22(12):2469-2476

In this prospective, randomized, double-blind, controlled trial patients with incurable cancer and weight loss greater than 5 pounds (2.3 kg) within 2 months (or physician-estimated caloric intake < 20 kcal/kg body weight/day) were randomly assigned to receive either an EPA containing nutritional supplement (ProSure) plus placebo megestrol acetate, megestrol acetate plus an isocaloric, isonitrogenous control nutritional supplement, or an EPA containing nutritional supplement plus megestrol acetate. The primary endpoint was a 10% weight gain from baseline between each of the EPA groups and the megestrol acetate plus control group.

Objective

To determine whether an EPA-containing nutritional supplement–either alone or in combination with megestrol acetate (MA)–improves weight, appetite, quality of life, and survival in advanced cancer patients with cancer-associated wasting, compared with MA alone.

Study Design

- **STUDY POPULATION**: Incurable malignancies, excluding brain, breast, ovarian, prostate, or endometrial cancer (n = 421; n = 141 EPA + placebo megestrol acetate group, n = 140 megestrol acetate + control group, n = 140 EPA + megestrol acetate group)
- **LENGTH OF STUDY**: 4 weeks
- **INTERVENTION**: 2 servings/day ProSure (240 mL/serving) or isocaloric, isonitrogenous control

Outcomes

- **Weight gain**. Both ProSure- and megestrol acetate-treated groups had more than one-third of patients gaining weight over the 4-week course. ProSure was as effective as megesterol acetate, and there were fewer side effects with ProSure.
- The megestrol acetate + control group had a greater percentage of patients with ≥ 10% weight gain (18%) compared to the EPA + megestrol acetate group (11%) and the EPA + placebo megestrol acetate group. This was statistically significant. However, when comparing % of patients with ANY weight gain, there were no statistically significant differences among the groups.
- No difference among groups in the QoL assessment.
- No difference among groups for length of survival.
- A greater incidence of impotence was noted in the megestrol acetate + control group.

Group	% with ≥ 10% baseline weight gain	% with ANY weight gain**
megestrol acetate + control	18%*	39%
EPA + megestrol acetate group	11%*	45%
EPA + placebo megestrol acetate group	6%	37

**P* = 0.004 vs EPA + placebo megestrol acetate group alone but no difference (*P* = 0.17) between the two megestrol acetate groups.
**statistics not provided

Study Conclusions

The authors conclude that ProSure alone or with megestrol acetate was no better than megestrol acetate alone.

Critical considerations on the use of a protein and energy dense omega-3 enriched sip feed in cancer patients

Capuano G, Pavese I, Satta F, Coiro G, Todi F, Zoffoli MV, Tosti M, Palladino A, Di Palma M
Rivista Italiana di Nutrizione Parenterale ed Enterale. 2005;23:43-46

Capuano and colleagues conducted a prospective, single-arm study in patients with cancer cachexia.

Objective

To determine the compliance and effects of ProSure on body mass index (BMI), body weight, ECOG performance status, prealbumin, and retinol binding protein in cancer patients.

Study Design

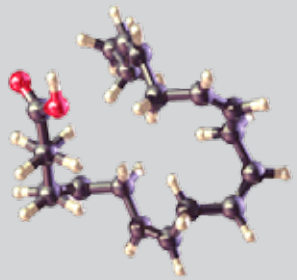
- **STUDY POPULATION**: Ambulatory patients with a variety of cancer types (n = 22)
- **LENGTH OF STUDY**: 4 weeks
- **INTERVENTION**: 2 servings ProSure (240 mL/serving)

Outcomes

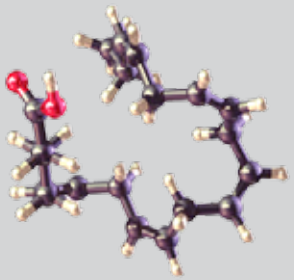
- A positive correlation was observed with supplement intake and both **weight gain**, 3 kg ± 1 (range 2-4 kg) and **improvement in performance status.**

Study Conclusions

The researchers concluded that patients' adherence to the recommended dose of supplements such as ProSure is critical to the prevention and treatment of cancer cachexia. Alterations or loss of taste, preference for foods or nutritional supplements may affect intake of supplements. Improvements in acceptability and palatability may help the treatment of cancer-related weight loss.



EPA - eicosapentaenoic acid



EPA - eicosapentaenoic acid

The use of a protein and energy dense eicosapentaenoic acid containing supplement for malignancy-related weight loss in children

Bayram I, Erbey F, Celik N, Nelson JL, Tanyeli A ***Pediatr Blood Cancer. 2009;52:571-574***

In a prospective, randomized, open-label study, Bayram and colleagues evaluated the effect of ProSure on cancer-related weight loss in children with leukemia or solid tumors who were undergoing chemotherapy. Weight changes, body mass index (BMI), and tolerance were monitored for 3 months, with a subset of patients followed an additional 6 months.

Objective

To evaluate the clinical effects of a protein and energy dense EPA containing oral supplement in pediatric cancer patients receiving active chemotherapy treatment.

Study Design

- **STUDY POPULATION**: The mean age of the children was 7.5 years. Pediatric patients with malignant disease (leukemia or solid tumors) receiving intensive chemotherapy (n = 52; ProSure = 33, control = 19)
- **LENGTH OF STUDY**: 3 months
- **INTERVENTION**: 2 servings ProSure (240 mL/serving) or usual dietary care

Outcomes

- After 3 months, only 6.1% of children in the ProSure group lost weight, compared to 47.4% of children in the control group (P = 0.001). Similarly, 12.1% of the children in the ProSure group had a lowered BMI, compared to 52.6% of children in the control group (P = 0.002). These differences were associated with a higher rate of cancer remission in the ProSure group compared to the control group (87.9% vs 63.2%, P = 0.036).

Study Conclusions

Children with malignant disease fed a protein and energy dense EPA containing oral supplement experienced a decrease in cancer-induced weight loss.

This is a navigatable book shelf. Click on the books to view each supporting publication.

This section includes summaries of 5 studies and 2 papers that support the use of fish oil in patients with cancer.

Summaries of three early studies that demonstrate the clinical benefits of using fish oil in patients with pancreatic cancer and generalized tumors are included. In addition, 2 recently published studies using supplemental fish oil in patients with lung cancer are summarized.

Two publications that are not clinical studies are also included: A summary of a recently published international consensus statement on the definition and classification of cancer cachexia and a minireview of studies that evaluated the role of eicosapentaenoic acid (EPA) on lean body mass (LBM) in cancer cachexia.

Supporting Publications

The effect of polyunsaturated fatty acids on the progress of cachexia in patients with pancreatic cancer

Wigmore SJ, Ross JA, Falconer JS, Plester CE, Tisdale MJ, Carter DC, Fearon KCH ***Nutrition. 1996;12(1):S27-S30***

Patients with unresectable adenocarcinoma of the pancreas (stage II-IV) and a history of weight loss were enrolled in this prospective, single-arm pilot study.

Objective:

To evaluate the effect of fish oil capsules, containing eicosapentaenoic acid (EPA), on nutritional parameters and acute phase response (APR) in cachectic patients with pancreatic cancer.

Study Design:

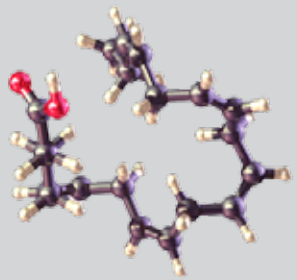
- **STUDY POPULATION**: Patients with unresectable adenocarcinoma of the pancreas (n = 18)
- **LENGTH OF STUDY**: 3 months
- **INTERVENTION**: 2 g/day fish oil capsules increased at weekly intervals by 2 g to a maximum dose of 16 g/day

Outcomes:

- Patients tolerated a median maximum dose of 12 g/day of fish oil. All patients were losing weight before the study (median 2.9 kg/month).
- After 3 months of supplementation, weight loss had been stopped or reversed in 14 of 18 patients (median weight change 0.3 kg/month).
- After 1 month of supplementation, CRP levels significantly decreased from 15 mg/L to 10 mg/L ($P < 0.002$); although following 3 months of supplementation, CRP levels had returned to presupplementation levels.
- One month of supplementation increased plasma EPA (from undetectable levels to a median of 5.3% total fatty acids) and DHA (from 3.5% to a median of 6.6% total fatty acids).
- There was no significant change in body water and body composition, and resting energy expenditure was stabilized.

Study Conclusions:

Supplementation with fish oil (2 g/day EPA) significantly altered the progression of cachexia in patients with pancreatic cancer. Following supplementation with fish oil, patients became weight stable (median 0.3 kg/month) compared with pre-study when they were losing weight at a median rate of 0.2 kg/month.



EPA - eicosapentaenoic acid

Dietary omega-3 polyunsaturated fatty acids plus vitamin E restore immunodeficiency and prolong survival for severely ill patients with generalized malignancy

Gogos CA, Ginopoulos P, Salsa B, Apostolidou E, Zoumbos NC, Kalfarentzos F ***Cancer. 1998;82:395-402***

Patients with generalized solid tumors were enrolled in this prospective, randomized, controlled study.

Objective:

To evaluate the effect of dietary omega-3 polyunsaturated fatty acids from fish oil plus vitamin E on the immune status and survival of well-nourished and malnourished patients with generalized malignancy.

Study Design:

- **STUDY POPULATION**: Patients with generalized solid tumors (n = 64)
- **LENGTH OF STUDY**: 40 days
- **INTERVENTION**: 18 g of fish oil capsules 3 times daily

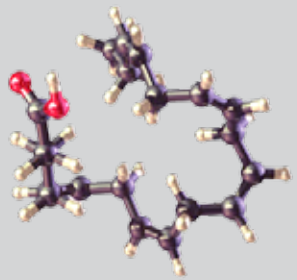
Outcomes:

No effect of omega-3 polyunsaturated fatty acids on body weight, serum albumin, or serum transferrin in either the well-nourished or malnourished group.

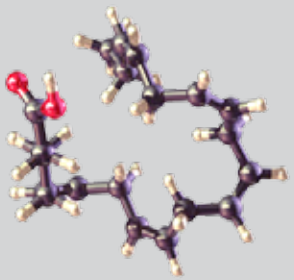
- A significant increase in the T helper/T suppressor lymphocyte ratio in the malnourished group.
- No significant differences in the production of IL-1 and IL-6 between the well-nourished and malnourished groups.
- Karnofsky Performance Status was significantly improved ($P < 0.01$) in the malnourished-treated group.
- Survival was significantly prolonged ($P < 0.001$) in the well-nourished group compared with the malnourished group. The best survival rates were found in the well-nourished supplemented group, and the worst survival rates were found in the malnourished placebo group.
- Supplementation with omega-3 fatty acids and vitamin E resulted in a significantly increased survival rate ($P < 0.025$) for all patients compared with placebo.

Study Conclusions:

Supplementation with fish oil (18 g/day omega-3 polyunsaturated fatty acids) had a significant immunomodulating effect and seemed to help prolong survival in malnourished patients with generalized malignancy.



EPA - eicosapentaenoic acid



EPA - eicosapentaenoic acid

Effect of oral eicosapentaenoic acid on weight loss in patients with pancreatic cancer

Wigmore SJ, Barber MD, Ross JA, Tisdale MJ, Fearon KCH ***Nutr Cancer. 2000;36(2):177-184***

Patients with unresectable adenocarcinoma of the pancreas were enrolled in this prospective, single-arm study.

Objective:

To evaluate the acceptability and effects of oral supplementation with high-purity eicosapentaenoic acid (EPA) in weight-losing patients with advanced pancreatic cancer.

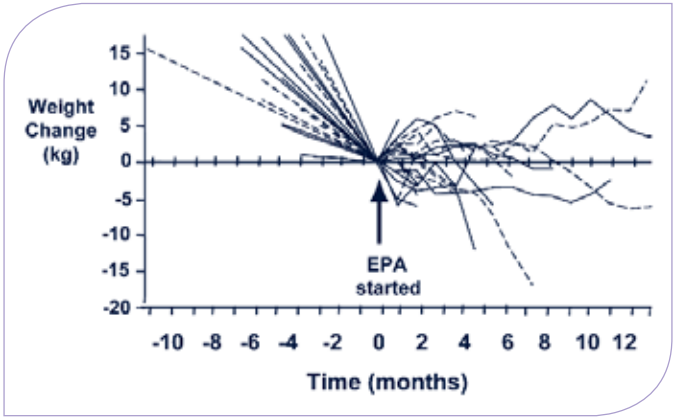
Study Design:

- **STUDY POPULATION**: Patients with unresectable adenocarcinoma of the pancreas (n = 26)
- **LENGTH OF STUDY**: 12 weeks
- **INTERVENTION**: Daily EPA supplementation starting at 1 g/day for the 1st week and increasing to a maximum of 6 g/day from week 4 to the end of the study

Outcomes:

- Before supplementation, all patients had been losing weight at a median rate of 2.0 kg/month and had lost a median of 13% of their usual body weight.
- A median weight gain of 0.5 kg/month (P = 0.0009) was observed after 4 weeks of supplementation.
- There were no significant changes in total body water, and the percentage of people with an elevated CRP did not increase.

WEIGHT CHANGES IN PANCREATIC CANCER PATIENTS (N = 26) WHO WERE GIVEN EPA



Study Conclusions:

As observed in the 1998 study conducted by Wigmore et al, highly purified EPA stabilized weight in people with pancreatic cancer and tempered the progression of weight loss. However, increasing the maximum daily dose of EPA from 2 g to 6 g did not appear to enhance the anticachectic effects.

Nutritional intervention with fish oil provides a benefit over standard of care for weight and skeletal muscle mass in patients with nonsmall cell lung cancer receiving chemotherapy

Murphy RA, Mourtzakis M, Chu QSC, Baracos VE, Reiman T, Mazurak VC ***Cancer. 2011;117:1775-1782***

Patients with nonsmall cell lung cancer (NSCLC) who were naïve to chemotherapy were enrolled in this open-label trial.

Objective:

To evaluate the effect of nutritional intervention with fish oil on weight and body composition against standard of care (SOC) during the course of chemotherapy.

Study Design:

- **STUDY POPULATION**: Patients with NSCLC (n = 40; fish oil group n = 16, standard of care group n = 24)
- **LENGTH OF STUDY:** 1st day of chemotherapy and continuing for the duration of chemotherapy
- **INTERVENTION**: 1-g gelatin capsules containing 2.2 g EPA 4 times per day or 7.5 mL liquid fish oil containing 2.2 g EPA once per day

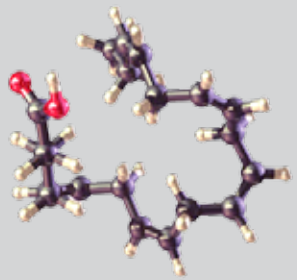
Outcomes:

Fish oil was well tolerated with no serious adverse events reported.

- Patients in the fish oil supplement group maintained their weight (0.5 ± 1.0 kg) whereas patients in the SOC group lost an average of -2.3 ± 0.9 kg; $P = .05$.
- Approximately 69% of patients in the fish oil supplement group gained or maintained muscle mass compared with only 29% of patients in the SOC group who maintained muscle mass.

Study Conclusions:

Nutritional intervention with 2.2 g fish oil per day appears to provide a benefit over SOC by maintaining weight and muscle mass during chemotherapy.



EPA - eicosapentaenoic acid

Supplementation with fish oil increases first-line chemotherapy efficacy in patients with advanced nonsmall cell lung cancer

Murphy RA, Mourtzakis M, Chu QSC, Baracos VE, Reiman T, Mazurak VC ***Cancer. 2011;117:3774-80.***

Patients with stage IIIB or IV nonsmall cell lung cancer (NSCLC) who were chemotherapy-naïve were enrolled in this open-label trial.

Objective:

To evaluate the effect of fish oil on response rate and clinical benefit from chemotherapy.

Study Design:

- **STUDY POPULATION**: Patients with NSCLC (n = 46; fish oil group n = 15, standard of care group n = 31)
- **LENGTH OF STUDY**: 1st day of chemotherapy and continuing for the duration of chemotherapy
- **INTERVENTION**: 1-g gelatin capsules containing 2.2 g EPA and 240 mg DHA 4 times per day or 7.5 mL liquid fish oil containing 2.2 g EPA and 500 mg DHA once per day

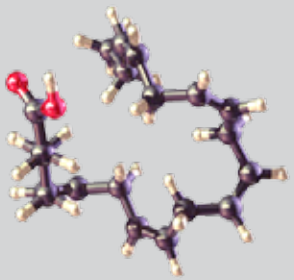
Outcomes:

Fish oil supplementation was well tolerated with no reported adverse events.

- The patients who received fish oil experienced an increased response rate and greater clinical benefit compared with the patients who received standard of care, (60.0% vs 25.8%, *P* = .008; 80.0% vs 41.9%, *P* = .02, respectively).
- The incidence of dose limiting toxicity did not differ between the groups (*P* = .46).
- There was a trend towards greater one-year survival in the fish oil group (60.0% vs 38.7%; *P* = .15).

Study Conclusions:

Compared with standard of care, supplementation of fish oil in patients with NSCLC undergoing chemotherapy resulted in increased chemotherapy efficacy without affecting toxicity and may contribute to increased survival.



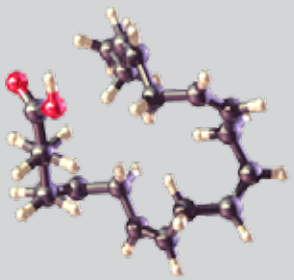
**EPA -
eicosapentaenoic acid**

Cover

Introduction

ProSure Clinical Studies

Supporting Publications



EPA - eicosapentaenoic acid

Definition and classification of cancer cachexia: an international consensus

Fearon K, Strasser F, Anker SD, Bosaeus I, Bruera E, Fainsinger RL, Jatoi A, Loprinzi C, MacDonald N, Mantovani G, Davis M, Muscaritoli M, Ottery F, Radbruch L, Ravasco P, Walsh D, Wilcock A, Kaasa S, Baracos VE ***Lancet Oncol. 2011 May;12(5):489-95***

A group of experts in clinical cancer cachexia (medical and surgical oncologists, palliative medicine specialists, and nutritionists) participated in a formal consensus process to develop a definition and classification of cancer cachexia.

Definition:

Cancer cachexia is a multifactorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. The pathophysiology is characterised by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism.

Diagnosis of cancer cachexia:

- Weight loss >5% over 6 months, or
- BMI <20 and weight loss >2%, or
- Appendicular skeletal muscle index consistent with sarcopenia (males <7.26 kg/m^2; females <5.45 kg/m^2) and weight loss >2%

Classification

STAGE

Precachexia

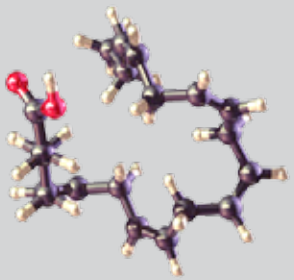
- Weight loss ≤ 5%
- Anorexia
- Metabolic changes

Cachexia

- Weight loss > 5%
- BMI <20 and weight loss > 2% or sarcopenia and weight loss > 2%
- Reduced food intake/systemic inflammation

Refractory cachexia

- Varying degrees of cachexia
- Procatabolic cancer disease not responsive to treatment
- Low performance score
- < 3 months life expectancy



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Influence of eicosapentaenoic acid supplementation on lean body mass in cancer cachexia

Murphy RA, Yeung E, Mazurak VC, Mourtzakis M ***Br J Cancer. 2011;105:1469-73***

A minireview was conducted of studies that evaluated the role of eicosapentaenoic acid (EPA) on lean body mass (LBM) in cancer cachexia. Initial study results suggested improvements in LBM with EPA supplementation. However, results from subsequent larger, phase III clinical trials showed minimal benefit with supplementation. This review discussed potential reasons for discrepancies in these study results with recommendations for future study designs to reduce discrepancies in outcomes.

The potential mechanism of action of EPA on LBM involves the effect of EPA directly and indirectly on muscle wasting and muscle anabolism. EPA's role in muscle anabolism appears to occur through its effect on sensitizing skeletal muscle to insulin. Muscle breakdown may be decreased by EPA's role in downregulating the acute-phase response and decreasing the expression of proteosome subunits. In an animal model of colorectal cancer, EPA and docosahexaenoic acid (DHA) were shown to reduce the side effects of chemotherapy. EPA and DHA have been shown to enhance tumor response to chemotherapy and to improve protein and calorie intake.

Early studies have shown benefits of EPA supplementation on LBM. However, subsequent phase III clinical trials did not show a benefit of EPA supplementation over placebo on LBM. More recent clinical trials have reported a benefit of EPA supplementation over control. Discrepancies in EPA study results during the last decade, may, in part, be explained by differences in study designs. In reviewing these studies, the authors looked at study compliance, measures of phospholipid (PL) EPA levels, assessment of LBM, and timing of intervention.

Compliance

Poor compliance to EPA supplementation and contamination between treatment arms have been noted in several studies.

Heterogeneity of plasma PL EPA following supplementation

To assess compliance to EPA supplementation, plasma PL EPA concentration is commonly measured. Studies have shown an increase in PL EPA post-supplementation; however, one study reported little or no change in a fourth of the patients despite reported compliance. It is unknown why EPA was not incorporated into cellular membranes. One theory centers around proximity to death, as it is has been reported that PL EPA concentration decreases as time of death nears.

Assessment of LBM

The authors discussed the methological limitations with different types of body composition assessment tools. Limitations with bioelectrical impedance (BIA) include the inability to distinguish between skeletal muscle and other lean tissue and the use of predictive equations to estimate lean tissue. The predictive equations used may not have been derived from cancer populations. When LBM was measured using dual-energy X-ray absorptiometry (DXA) and BIA, small but clinically significant changes in LBM were observed using DXA but not BIA. Therefore, in previous EPA supplement studies, changes in LBM may not have been observed when BIA was used. A new area of research involves the use of CT imaging to identify gain in LBM as it relates to gain in skeletal muscle and visceral organs. CT imaging is routinely used to stage disease and in follow-up and can discriminate between muscle, adipose tissue, bone, and other organs. Currently, only one EPA supplement study has utilized CT imaging to evaluate change in skeletal muscle.

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Influence of eicosapentaenoic acid supplementation on lean body mass in cancer cachexia *(continued)*

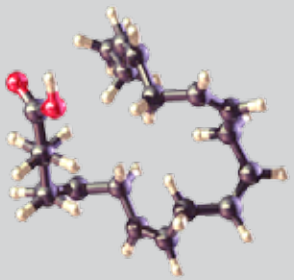
Murphy RA, Yeung E, Mazurak VC, Mourtzakis M ***Br J Cancer. 2011;105:1469-73***

Timing of intervention with EPA

In accordance with the recently published cachexia classification system, in order to minimize muscle loss, interventions should be initiated during the pre-cachexia stage. In previous EPA studies, patients may have been enrolled when they were in the refractory cachexia stage. Patients in this stage often have significant disease progression and shorter median survival, such that EPA supplementation may be less effective.

In conclusion, the authors noted that positive results from previous studies may have been due to features of the study designs. For the design of future EPA supplementation trials, the authors made the following recommendations:

- To improve study compliance, offer patients a choice in the format of the supplement (capsules or liquid, parenteral or enteral)
- When analyzing data, consider stratifying outcomes based on PL EPA levels to allow for differences in incorporation of EPA into PL
- Utilize CT image analysis whenever possible to precisely quantify skeletal muscle
- In order to see a beneficial effect, provide EPA supplementation earlier in the disease process, rather than later when muscle loss is accelerated



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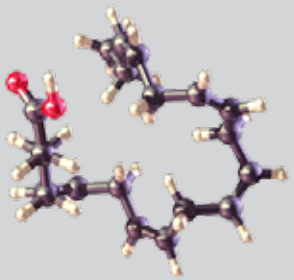

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