EPA Incorporation and Immune responses after nutritional supplementation in Cancer patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25291

Source
NTR

Brief title
EIIC

Health condition

Cancer patients

Sponsors and support

Primary sponsor: Danone Research ¨C Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research ¨C Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

1. Incorporation kinetics of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in membrane phospholipids of white and red blood cells and plasma phospholipids;

2. Effects on ex vivo immune responses in cancer patients.

Secondary outcome

Effects of nutritional supplementation on inflammatory status.

Study description

Background summary

The purpose of this study is to assess the effect of the study product (an energy dense protein rich oral supplement enriched with fish oil, fibre and leucine) on incorporation kinetics of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in membrane phospholipids of white and red blood cells and plasma phospholipids and to assess effects on ex vivo immune responses in cancer patients. It is expected that one week of supplementation with the study product will contribute to an improved immune response and to incorporation of EPA and DHA in white and red blood cells and plasma.

Study objective

It is expected that one week of supplementation with the study product will contribute to an improved immune response and to increased incorporation of EPA and DHA in white and red blood cells and plasma.

Study design

8 days intervention; study visit at start and at end of intervention.

Intervention

1. Intake of study product;

2. Duration of intervention: 8 days;

3. Intervention group: cancer patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pathologically confirmed solid tumor(s);

2. Body Mass Index 18.5 - 30 kg/ m2;

3. Willing and able to abstain from use of alcohol, smoking, fish (fatty fish e.g. salmon, mackerel, herring, eel), fish oil containing supplements and vitamin supplements or oil supplements (e.g. evening primrose oil);

4. Age ¡Ý 18 years;

5. Written informed consent.

Exclusion criteria

1. Surgery, radiotherapy, chemotherapy and or hormone therapy less than 2 months ago or planned within the study period;

2. Use of supplements containing fish oil, vitamins or oil supplements (e.g. evening primrose oil) during the previous 4 weeks;

3. Intolerance or allergy to dairy products, fish, or other ingredients of the study products;

4. Altered immune function (e.g. caused by major active infection, autoimmune disease, active allergy, rheumatoid arthritis, inflammatory bowel diseases, multiple sclerosis, or by use of medication such as immunosuppressive drugs, immunomodulators including NSAIDs, or corticosteroids (unless not considered to be systemically available) as listed in appendix I);

5. Currently smoking and smoking in the past 6 months;

6. Life expectancy < 3 months;

7. ECOG performance status > 2;

8. Dependence on tube feed or parenteral nutrition in the last 4 weeks;

9. If pre-menopausal female: pregnant or lactating;

10. Dementia or altered mental status that would prohibit the understanding and giving of informed consent;

11. Any other medical condition that may interfere with the safety of the patient or the outcome parameters, in the investigator's judgement;

12. Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements (e.g. alcohol abuse).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2009
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	26-08-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1854
NTR-old	NTR1966
CCMO	NL27755.072.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A