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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25291

Bron
NTR

Verkorte titel
EIIC

Aandoening

Cancer patients

Ondersteuning

Primaire sponsor: Danone Research ¨C Centre for Specialised Nutrition
Overige ondersteuning: Danone Research ¨C Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

1. Intake of study product;

2. Duration of intervention: 8 days;

3. Intervention group: cancer patients.

Contactpersonen

Publiek

ziekenhuisapotheek MCA, Postbus 501
W. Graaf de

Alkmaar 1800 AM
The Netherlands

Wetenschappelijk

ziekenhuisapotheek MCA, Postbus 501
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The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-02-2009
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A