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

Gepubliceerd: 02-12-2009 Laatst bijgewerkt: 13-12-2022

It is expected that 8 days 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-OMON21909

Bron
NTR

Verkorte titel
EIIC-RT

Aandoening

Cancer patients receiving RadioTherapy

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. Percentage EPA and DHA of total phospholipid fatty acids of cell membranes of white and red blood cells and plasma;
2. Ex vivo pro-inflammatory cytokine and prostaglandin E2 (PGE2) production in lipopolysaccharide (LPS)-stimulated whole blood.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial an Active sip feed will be compared with a Routine sip feed in cancer patients receiving radiotherapy. The study product will be used for eight days. Blood samples will be collected at day 1 and 8.

Doel van het onderzoek

It is expected that 8 days 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

Day 1 and day 8.

Onderzoeksproduct en/of interventie

Intake of study product; duration of intervention: 8 days.

Intervention group: cancer patients receiving radiotherapy.

An Active sip feed will be compared with a Routine sip feed.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pathologically confirmed solid tumor(s);

2. Receiving radiotherapy during the study;

3. Body Mass Index 18.5 ¨C 30 kg/ m2;

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

5. Age ¡Ý 18 years;

6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Surgery and / or chemotherapy within the past 6 weeks;

2. Previous radiotherapy (before current treatment cycles) within the past 6 weeks;

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

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

5. 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)). See Appendix I for the immune modification medication list;

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

7. Life expectancy < 3 months;

8. ECOG performance status > 2;

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

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

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

12. Any other medical condition that may interfere with the safety of the patient or the outcome parameters, in the investigator¡¯s judgment;

13. 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:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	02-12-2009
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-12-2009
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	NL2004
NTR-old	NTR2121
Ander register	Danone Research : onc.2.c/h
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A