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

No registrations found.

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

Summary

ID

NL-OMON21909

Source
Nationaal Trial Register

Brief title
EIIC-RT

Health condition

Cancer patients receiving RadioTherapy

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. 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.

Secondary outcome

Serum cytokine and C-reactive protein (CRP) levels.

Study description

Background summary

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.

Study objective

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.

Study design

Day 1 and day 8.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	02-12-2009
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion Date:	02-12-2009
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	NL2004
NTR-old	NTR2121
Other	Danone Research : onc.2.c/h
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A