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Effects of enteral nutrition enriched with omega-3 fatty acids on outcome in non-small cell lung cancer patients

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 13/05/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR264

Study information

Scientific Title

Acronym
longdrinkstudy

Study objectives
A nutritional supplement enriched with omega-3 fatty acids has beneficial effects on functional and nutritional parameters and on quality of life (QOL) in non-small cell lung cancer (NSCLC) patients undergoing chemo(radiation)therapy and lung resection, compared to a control energy-dense nutritional supplement without omega-3 fatty acids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committees

Study design
Randomised double blind placebo-controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non-small cell lung cancer (NSCLC)

Interventions
Group A (n = 20) will receive two packages per day of a nutritional supplement with 2 g eicosapentaenoic acid (EPA).
Group B (n = 20) will receive two packages per day of a control nutritional supplement.

Total duration of treatment = 8 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omega-3 fatty acids

Primary outcome measure
1. Muscle strength
2. Immune status
3. Nutritional status
4. Cancer cachexia

Secondary outcome measures
1. Quality of life (QOL)
2. Physical activity level (PAL)
3. Post-operative complications and survival

Overall study start date
01/03/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
1. Aged 18 to 75 years
2. Diagnosis NSCLC stage III
3. Resolved treatment plan: neo-adjuvant chemo(radiation)therapy during 6 weeks and, dependent on disease regression, tumour resection
4. Life expectancy greater than 3 months
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria

1. Surgery, chemo- or radiation therapy during the previous month
2. Oedema or ascites
3. Use of fish oil supplements during the last month
4. Use of high dose corticosteroids (low dose, inhalation steroids and/or local use is permitted)
5. Other active medical conditions (major gastrointestinal disease, chronic renal failure, uncontrolled diabetes mellitus, human immunodeficiency virus [HIV])

Date of first enrolment
01/03/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor type
University/education

Website
http://www.vumc.nl

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories (Netherlands)

Alternative Name(s)
Abbott, Abbott U.S., Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration