

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

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| Submission date 20/12/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 20/12/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 13/05/2009 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr B. van der Meij

Contact details
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
b.vandermeij@vumc.nl

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