Prevalence and biomarkers of pre-cachexia and cachexia in advanced cancer patients scheduled for treatment with chemotherapy

Published: 06-10-2011
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- To determine the prevalence of (pre)cachexia - To determine whether potential biomarkers of pre-cachexia can be identified

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON35709

Source
ToetsingOnline

Brief title
(Pre-)cachexia in cancer patients undergoing chemotherapy

Condition

- Appetite and general nutritional disorders
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, Neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Fonds Nuts Ohra

Intervention

Keyword: Cachexia, Cancer, Chemotherapy, Pre-cachexia

Outcome measures

Primary outcome

Prevalence of pre-cachexia and cachexia.

Secondary outcome

-The prevalence of pre-cachexia related to tumour type

-Potential biomarkers of pre-cachexia will be investigated

Study description

Background summary

Cachexia is a frequently observed syndrome in cancer patients. It reversely impacts quality of life and is linearly and prognostically related to clinical outcome but cannot be fully reversed by conventional nutritional therapy. In contrast to cachexia, pre-cachexia is expected to be a still reversible state that may respond to nutritional intervention. Recently, an expert-opinion of pre-cachexia has been put forward that can be used for the early identification, and subsequently for the early treatment, of pre-cachexia. The current proposal aims to study the prevalence of pre-cachexia and cachexia, to identify patient groups at increased risk and to study the association between pre-cachexia and several biomarkers.

Study objective

- To determine the prevalence of (pre)cachexia
- To determine whether potential biomarkers of pre-cachexia can be identified

Study design

This study is an observational, cross-sectional study.

Study burden and risks

The burden and risks for the participants is light: an interview of at maximum 30 minutes, including 3 small self-administered questionnaires, 2 VAS-scales and a measurement of body composition. In addition, patients are asked for extra blood collection of 2 tubes during routinely collected blood in fasted state to identify potential biomarkers of pre-cachexia and cachexia

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adults (> 18 years);
- Stage III/IV non small cell lung cancer
- Treatment plan: palliative chemotherapy or chemoradiation

Exclusion criteria

-Ascites (for which treatment is necessary) or serious pitting edema;
-Chemotherapy treatment in the past month;
-Not able to speak the Dutch language;
-Pregnancy.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	06-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24155
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37535.029.11
OMON	NL-OMON24155