Onderzoek naar (signaalstoffen van) de voedingstoestand bij patienten met een tumor in de long, borst, prostaat of dikke darm.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24155

Source
Nationaal Trial Register

Health condition

precachexia, cachexia, cancer

precachexie, cachexie, kanker

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Nuts Ohra fund

Intervention

Outcome measures

Primary outcome

To determine the prevalence of (pre)cachexia (based on the current definition) in patients with advanced cancer scheduled for treatment with chemotherapy.

Secondary outcome

1. To determine the prevalence of pre-cachexia and cachexia related to the type of tumour (part 1, not-WMO);

2. To determine the reproducibility and validity of the measurement of pre-cachexia and cachexia at two consecutive time points (at minimum one week apart from each other) in one patient (part 1, not-WMO);

3. To determine whether potential biomarkers of pre-cachexia can be identified in a subgroup of cancer patients with stage III/IV non-small cell lung cancer (part 2, WMO).

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 explore potential biomarkers of pre-cachexia.

Study objective

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 explore potential biomarkers of pre-cachexia.

Study design

Cross-sectional design (try for 2 measurements with one week in between).

Intervention

Two interviews of at maximum 30 minutes (with one week in between), including 3 small self-

administered questionnaires, 2 VAS-scales and a measurement of body composition. In addition, 60 patients with stage III/IV non-small cell lung cancer are asked for extra blood collection during (two tubes) routinely collected blood in fasted state to identify potential biomarkers of pre-cachexia and cachexia.

Contacts

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Eligibility criteria

Inclusion criteria

4.2.1 Inclusion criteria for cohort (part 1, not-WMO):

1. Adults (> 18 years);

2. Advanced breast cancer, colorectal cancer, hormone refractory prostate cancer or stage III/IV non small cell lung cancer;

3. Treatment plan: Palliative chemotherapy or in the case of stage III NSCLC: chemoradiation.

Exclusion criteria

1. Ascites (for which treatment is necessary) or serious pitting edema;

2. Chemotherapy treatment in the past month;

3. Not able to speak the Dutch language;

4. Pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2011
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-10-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35709
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2947
NTR-old	NTR3094
CCMO	NL37535.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35709

Study results

Summary results
N/A