Changes in body composition in patients with cancer in the upper airway and digestive tract: a prospective study

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

Summary

ID

NL-OMON34021

Source
ToetsingOnline

Brief title
Changes in body composition in head and neck cancer patients

Condition

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

Synonym
malnutrition, undernutrition

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: body composition, head and neck cancer, malnutrition

Outcome measures

Primary outcome

Primary outcome measurement is changes in body composition (fat mass and lean body mass), assessed by:

- DEXA (dual energy x-ray absorptiometry).

- anthropometerics: skinfold measurements (triceps, biceps, subscapula, supra-iliaca), upper arm (muscle) circumference

- hand grip strength

- bio-electrical impedance analysis (BIA)

Secondary outcome

Secondary outcome measurements are:

- serum levels leptin, adiponectin, FT3, FT4, TSH, IGF-1, IGF-BP3, albumin, prealbumin, transferrin, total cholesterol, CRP, IL-1, IL-6, TNF-α and hemoglobine

- presence of symptoms/complaints

- performance score

Study description

Background summary

Patients with a tumor in the upper airway and digestive tract are at high risk for malnutrition. It is not clear which body compartments are affected in the period during and after treatment. Until now, prediction of malnutrition is not possible. As a result of that, it is not possible to evaluate in which patients

prophylactic placement of a PEG tube is indicated or not.

Study objective

Primary aim of this study is to assess changes in body composition in patients with a carcinoma in the larynx, pharynx or oral cavity, in the period during and after treatment.

Secundary aims of this study are:
- to assess predictive factors for malnutrition or changes in body composition, for example biomarkers, TNM classification, tumor localization, irradiation field, presence of malnutrition before treatment, performance score and complaints/symptoms
- to assess to which extent the results of body composition measurements are related to each other.

Study design

In the period during and after treatment, body composition of the patients will be assessed by DEXA, bioelectrical impedance analysis, anthropometric measurements and hand grip strength. Furthermore, blood samples will be taken from the patients three times and nitrogen balance will be assessed, to investigate if (changes) in biomarkers and presence of catabolism are related to changes in body composition during and after treatment. Risk factors like symptoms and complaints and performance score are assessed to analyse if they are related to malnutrition.

Study burden and risks

No significant health risks are expected from participation in this study. Radiation exposure induced by DEXA is very low (0.002 - 0.005 mSv) and is lower than the permitted dose of 5 mVs per year.

The extra burden for the participant consists of:
- 3 times blood collection of 15 ml = 45 ml during the entire investigation. Measurement of FT3, FT4, TSH, albumin, prealbumin, transferrin, total cholesterol and CRP are part of routine measurements.
- 3 times DEXA
- 5 to 6 anthropometric measurements , frequency depends on type of treatment: body weight, upper arm (muscle) circumference, 4 skinfold measurements
- 5 to 6 times hand grip strength
- 3 times BIA
- 3 times dietary history

Contacts

Public
Academisch Medisch Centrum

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- malignant tumour in the upper digestive and airway tract: larynx, pharynx or oral cavity
- curative treatment with surgery and postoperative radiotherapy, or radiotherapy, or chemoradiation
- age 18 year or above
- caucasian race
- good understanding of dutch language

Exclusion criteria

- palliative treatment
- tumor in other region than head and neck region (either secondary primary tumor or

metastasis)
- amputated arm(s)/leg(s)
- oedema as a result of cardial failure, ascites, nefrological or hepatic dysfunction
- orthopedic prosthesis (hip or knee)
- pacemaker
- dementia/mental dysfunction

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL14839.042.07