

Lichamelijke activiteit en energieverbruik van hoofdhalskanker patiënten.

No registrations found.

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

Summary

ID

NL-OMON22477

Source

Nationaal Trial Register

Brief title

PAP studie

Health condition

physical activity, energy expenditure, Head and neck cancer, malnutrition / lichamelijke activiteit, energiebalans, hoofdhalskanker, ondervoeding

Sponsors and support

Primary sponsor: Umcg Groningen, the Netherlands

Hanze university of applied science, Groningen, the Netherlands

Source(s) of monetary or material Support: Umcg Groningen, the Netherlands

Hanze university of applied science, Groningen, the Netherlands

Intervention

Outcome measures

Primary outcome

Daily step count (steps/day)

Measured energy expenditure (in kcal and METs)

Secondary outcome

Types of physical activity

Mass/fat-free mass (kg)

Muscle strength (number of stand ups)

Estimated energy expenditure (kcal)

Study description

Study objective

This study primarily aims to explore changes in physical activity pattern and energy expenditure in head and neck cancer patients, during and after treatment with surgery with or without (chemo)radiation.

The following primary null hypotheses will be tested in this study:

Physical activity of head and neck cancer patients treated with surgery, with or without postoperative (chemo)radiation, does not decrease during treatment period.

Total and resting energy expenditure of head and neck cancer patients treated with surgery, with or without postoperative (chemo)radiation, does not change during treatment period.

Measured energy expenditure does not differ from estimated energy expenditure in head and neck cancer patients treated with surgery, with or without postoperative (chemo)radiation.

The secondary aim of this study is to gain insight in perceived exercise barriers and facilitators, and exercise preferences of head and neck cancer patients.

Study design

Head and neck cancer patients will be assessed three times: 1) one week before start of treatment, 2) six weeks after end of treatment, and 3) four months after end of treatment.

Intervention

Not applicable: observational study

Measurements:

Physical measurements during the study:

Body weight

Length

Muscle mass/fat-free mass: mid upper arm muscle circumference (by means of mid upper arm circumference and triceps skinfold), thigh and calf circumference, bio-electrical impedance analysis

Muscle strength: hand grip strength (Jamar hand grip dynamometer), chair to stand test

Resting energy expenditure: indirect calorimetry (Cosmed K4b2)

Questionnaires:

Malnutrition: Patient-Generated Subjective Global Assessment (PG-SGA)

Frailty: Frailty Instrument for Primary Care of the Survey of Health, Ageing and Retirement in Europe (SHARE-FI)

Fatigue: MVI20

Self efficacy: Exercise Self Efficacy Scale

Self regulation: Self regulation Questionnaire Exercise

Motivation: Stage of Change Exercise

Performance status: WHO performance status scale

Tumor- and treatment-related symptoms: EORTC QLQ-HN35

Contacts

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Eligibility criteria

Inclusion criteria

- Newly diagnosed T1, T2, T3 or T4 malignancy in the oral cavity, larynx, oro- or

hypopharynx, to be treated with surgery with or without (chemo)radiation

- Age: at least 18 years
- Able to understand and speak the Dutch language

Exclusion criteria

- Second primary tumor, outside the head and neck region
- Wheel chair dependency
- Comorbidity with a contra-indication for physical exercise
- Severe cognitive disabilities
- Skin allergy or highly sensitive skin
- Palliative treatment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	23
Type:	Actual

Ethics review

Positive opinion

Date: 01-10-2014

Application type: First submission

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
NTR-new	NL4676
NTR-old	NTR4828
Other	METC UMCG : METC 2012/063

Study results