

Lichamelijke activiteit en energieverbruik van hoofdhalsskanker patiënten.

Gepubliceerd: 01-10-2014 Laatste bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22477

Bron

Nationaal Trial Register

Verkorte titel

PAP studie

Aandoening

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

Ondersteuning

Primaire sponsor: Umcg Groningen, the Netherlands

Hanze university of applied science, Groningen, the Netherlands

Overige ondersteuning: Umcg Groningen, the Netherlands

Hanze university of applied science, Groningen, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Daily step count (steps/day)

Measured energy expenditure (in kcal and METs)

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Hanze University of Applied Sciences

Eyssoniusplein 18
M. Sealy
Groningen 9714 CE
The Netherlands
050-5953604

Wetenschappelijk

Hanze University of Applied Sciences

Eyssoniusplein 18
M. Sealy
Groningen 9714 CE
The Netherlands
050-5953604

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	23
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 01-10-2014

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4676
NTR-old	NTR4828
Ander register	METC UMCG : METC 2012/063

Resultaten