Analysis of food reward system and taste perception in cachexia induced by acute or chronic disease

Published: 30-12-2015
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To study activity in the reward-circuitry of the brain in patients suffering from cachexia induced by cancer.

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

Summary

ID

NL-OMON47837

Source
ToetsingOnline

Brief title
Food reward and taste perception in cachexia

Condition

- Appetite and general nutritional disorders
- Miscellaneous and site unspecified neoplasms benign
- Respiratory tract neoplasms

Synonym
Anorexia, Cachexia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anorexia, Cachexia, Cancer, Taste perception

Outcome measures

Primary outcome

The main endpoint of this study is neural representations of taste stimuli.

Secondary outcome

Secondary endpoints are the relation between brain reward-related activity, anorexia based on a dietary questionnaire and in LAHNSCC patients only, the relation between taste perception and food reward related activity and degree of recovery after chemoradiation (CRT).

Study description

Background summary

Cachexia, i.e. unintended loss of skeletal muscle- and fat mass, is common in the cancer trajectory. Frequencies ranges up to 54% in lung cancer and 52% in head and neck cancer, and 86% in pancreatic cancer. Cachexia is not only an independent determinant of mortality but also influences tumor treatment and greatly influences quality of life. Patients with cachexia are often hypermetabolic, which should be compensated by dietary intake. However, it is acknowledged that dietary intake is often insufficient to meet elevated energy requirements, due to disease or treatment induced anorexia, i.e. loss of appetite. Elucidating underlying mechanisms of disease induced anorexia may provide new insights to optimize nutritional support in cachectic patients.

Study objective

To study activity in the reward-circuitry of the brain in patients suffering from cachexia induced by cancer.

Study design

cross-sectional study

Study burden and risks

The effective radiator dose of the DEXA scan is, depending on the duration of the scan (size of the body) between 0.001-0.007 mSv, which is neglectable in comparison to the yearly natural background dose in The Netherlands, which is 1-2 mSv. The risks of fMRI-scanning are negligible because it is a magnetic field, does not involve ionizing radiation and does not require contrast agents or anesthesia. The other measurements and procedures have very low risks.

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

Head and Neck Cancer (HNC) patients treated with concurrent chemoradiation or bioradiation

with curative intent.
-Treatment completion 2-3 months ago
-70>= age >=18;Healthy controls
-Matched for age, gender, smoking behaviour, and scanning hour of the day.

Exclusion criteria

For all groups:
- Contra-indications for fMRI examination (operation to your head or brain in the past; implanted electronic devices, for instance a pacemaker, neurostimulator, cochlear or hearing implant; insulin pump under your skin; pregnant subjects, claustrophobia; pregnancy; metal parts in your body (except from teeth filling and connectors): implants; brain vessel clamps, prostheses, intra-uterine device, metal splinter in the eye, metal braces or other metal objects, permanent eye make-up)
- Pregnancy
- Psychiatric or other disorders likely to impact on informed consent
- Presence of brain metastasis (screening is not mandatory)
- Medical history of cerebrovascular accident, brain tumour, brain metastasis
- Previous radiotherapy to brain, both stereotactic and whole brain radiotherapy
- Memory problems
- Current use of tube feeding or parental nutrition
- Patients with an active second malignancy
- Patients unable to lie still for 2 hours
- Unable to complete the cognitive task in the imitation scanner
- Allergy to gluten-, milk- or wheat products
- Self-reported hyperthyroidism
- Current use of appetite stimulant medications
- Recurrent head and neck cancer (rHNC)
- Previously administered systemic anti-tumor therapy
- Reirradiation setting
- Analphabetic
- Mini mental state examination score <21
- Concurrent neurological disease (e.g. morbus Parkinson)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	30-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-07-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL54799.068.15

Study results

Date completed: 18-02-2022

Actual enrolment: 5

Summary results
Trial ended prematurely