Brown adipose tissue activity in lung cancer

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To study the effect of early tumour development on brown adipose tissue activity

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

Summary

ID

NL-OMON37755

Source
ToetsingOnline

Brief title
Brown adipose tissue activity in lung cancer

Condition

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

Synonym
Wasting, Weight loss

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Donatie De Weijerhorst Stichting

Intervention

Keyword: brown fat, cachexia, Lung Cancer, PET-CT

Outcome measures

Primary outcome

BAT volume and intensity in kBq/SUV in the presence (before operation) compared to absense (after operation) of lung cancer, as determined by 18 F-FDG PET-CT scanning.

Secondary outcome

Second primary endpoint are the effects on energy expenditure, body core temperature, skin surface temperature, body composition and serum leverls of CRP and selected hormones that influence BAT activity

Study description

Background summary

Evidence by rodent studies in tomour models with cachexia have shovn an association between significant weight loss and significant degree of BAT thermogenic activation, providing evidence of BAT activation in tumour-bearing mice with cachexia. Activity of brown adipose tissue (BAT)in adult humans has only recently been discovered by the introduction of 18F-FDG PET-CT. Moreover, white dispose cells can directly transdifferentiate into brown adipose cells, the so-called BRITE cell recruitment. The observation of BAT in oncology patient staging by 18F-FDG PET-CT scanning as well asthe strong correlation between BAT activity and body mass index (BMI) has prompted the revisit of a possible role of BAT activation in human patients cancer cachexia. W hypothesize that an abnormal thermogenic activity exists in cancer patients through the inappropriate stimulation by the hypothalamas and BAT activity that normalizes after complete resection of the tumour

Study objective

To study the effect of early tumour development on brown adipose tissue

activity

Study design

Determine BAT activity iin cancer by use of PET-Imaging in a prospective study design

Study burden and risks

The Absorbed radiation dose of the FDG-PET-CT scan technique (administration of 74 MBq of 18F-FGD, total-body scan) is 3,7 mSv per scan (ICRP 103, berekening met computer programma CT-Expo versie 2.0). Subjects will be scanned twice, which is considered as a low risk. The subcutaneous fat biopsy is a minimally invasive procedure producing little discomfort

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

Resectable non-small cell lung cancer (NSCLC)
Age 40-70 years
Gender: male and female
Caucasians
Non-obese persons, i.e. Body Mass Index (BMI) <30 kg/m2

Exclusion criteria

Primary
• Body Mass Index > 30 kg/m2
• Medically treated Diabetes mellitus (oral anti-diabetics, insulin)
• Severe COPD and/or heart failure
• Patients with severe clotting disorder
• Patients with a second malignancy, either active or in previous medical history
• Thyroid disorders
• Psychological unstable persons presumed unfit to perform the measurements, including claustrophobia
• Patients with shortness of breath in rest
• Persons unable to lie or sit still for1-2 hours
• Pregnant subjects
• Subjects that received high doses of radiotherapeutic radiation of the neck and/or upper chest in their medical history
• Persons that received cervical of thoracic sympathectomy or have a nerve dysfunction which is likely to influence sympathetic nerves
• The use of the medication that influences the sympathetic nerve system: ß-blockers, α-blockers, central anti-hypertensives, certain anti-depression drugs (MAO inhibitors, tricyclic anti-depressives) reserpine, cocaïne, calciumblockers, labetalol, certain tranquillizers (fenothiazines)
• Exclusion criteria for core temperature measurement:
-In any patient whose body weight is less than 40 kg
-In the presence of any known or suspected obstructive disease of the gastrointestinal tract
-In any patient exhibiting or having a history of disorders or impairment of the gag reflex
-In any patient with previous gastrointestinal surgery
-In any patient having structural and/or functional disorders of the esophagus
-In any patient who might undergo Nuclear Magnetic Resonance (NMR) or MRI scanning during the period that the CorTemp* Disposable Temperature Sensor is within the body.
-In any patient with hypo motility disorders of the gastrointestinal tract
-In any patient having a cardiac pacemaker or other implanted electro medical device.;Secondary
• Unsuccesful complete macro- and microscopic resection of the lung tumor
• Presence of tumor recurrence on the second PET-CT scan

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2012
Enrollment:	13
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-07-2012
Application type:	First submission
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	NL39941.068.12
Other	Volgt bij goedkeuring