Brown adipose tissue activity and thyroid hormone

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To study the effect of thyroid hormone and thyroid-stimulating hormone on brown adipose tissue activity.

Ethical review	Approved WMO
Status	Pending
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON37371

Source
ToetsingOnline

Brief title
Brown adipose tissue activity and thyroid hormone

Condition

- Thyroid gland disorders
- Appetite and general nutritional disorders

Synonym
brown adipose tissue, thyroid carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw TOP 91209037

Intervention

Keyword: brown adipose tissue, obesity, thyroid gland

Outcome measures

Primary outcome

The main endpoint of this study is the effect of thyroid hormone and

thyroid-stimulating hormone on BAT activity in kBq and SUV.

Secondary outcome

Secondary endpoints are the effects of thyroid hormone and thyroid-stimulating

hormone on energy metabolism, body composotion, plasma values of thyroid

hormone, body core temperature, skin surface temperature and skin perfusion.

Study description

Background summary

During the last decades, research in possible therapies for existing obesity and developmental factors causing obesity has explosively increased. Recently renewed interest aroused for a tissue playing a possible role in both development and therapy for obesity: brown adipose tissue (BAT).
To define the relation between BAT and thyroid hormone, we set up the following research protocol. In this protocol BAT activity will be determined in subjects that underwent thyroidectomy for well-differentiated thyroid carcinoma.

Study objective

To study the effect of thyroid hormone and thyroid-stimulating hormone on brown adipose tissue activity.

Study design

Determine BAT activity after thyroidectomy in well-differentiated thyroid carcinoma patients.

Study burden and risks

The absorbed radiation dose from the FDG PET-CT scan after administration of 74 MBq of 18F-FDG is 2.8 mSv. The clinical treatment program requires a I124 PET-CT scan (182mSv) and a I131 ablation therapy (41625 mSv) of possible thyroid gland remnants. The additional radiation dose from measurements in this study is considered low in comparison to the standard radiation dose given for regular therapy.

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

- Male or postmenopausal females undergoing a total thyroidectomy for well-differentiated thyroid carcinoma
- Age 18-65 years
- Stable physical activity levels for at least six months

- Note: In case of use of anticoagulation, the dose will be adjusted according to plasma thyroid hormone values.

Exclusion criteria

- Psychological unstable subjects (as judged by the treating medical specialist)
- Subjects with mental retardation (as judged by the treating medical specialist)
- Subjects with severe behavior disorders (as judged by the treating medical specialist)
- Pregnant subjects
- The use of the following medication is an exclusion criterium;
o ß-blockers
- Participation in an intensive weight-loss program or vigorous exercise program during the last year before the start of the study
- Abuse of drugs and/or alcohol
- Severe diabetes which requires application of insulin or patients with diabetes-related complications
- Patients that have donated blood in the past 6 months

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):	01-04-2012
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-03-2012
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	NL39146.068.11