Long-term effects of bariatric surgery.

No registrations found.

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

Summary

ID

NL-OMON29394

Source
Nationaal Trial Register

Health condition

obesity
metabolic syndrome
bariatric surgery
dopamine receptors

obesitas
metabool syndroom
bariatrische chirurgie
dopamine receptoren

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: (volgt)

Intervention

Outcome measures

Primary outcome

Striatal dopamine D2/3 receptor availability.

Secondary outcome

1. Plasma levels of several hormones, metabolites and peptides involved in appetite regulation and glucose metabolism;

2. Behavioral parameters (measured via questionnaire and computer task).

Study description

Background summary

Rationale:

Bariatric surgery is the only effective way to induce sustained weight loss and reversal of the obesity-induced changes in lipid and glucose metabolism. Insight into the mechanisms underlying these highly desirable effects is crucial in the development of future treatment modalities for metabolic syndrome that do not involve the risks associated with surgery. Furthermore, gaining insight into the association between obesity and reduced striatal dopamine D2/3 receptor availability may provide valuable insight into the development of obesity and the metabolic syndrome and aid in the development of future treatment modalities.

Objective:

To determine whether the reduced striatal dopamine D2/3 receptor availability in morbidly obese women is reversed by long term weight loss after bariatric surgery. In addition, behavioral parameters and regulating factors involved in appetite regulation and glucose homeostasis will be studied and compared to data obtained prior to surgery and 6 weeks after surgery in an earlier study with the same participants. These regulatory factors will be correlated to changes in striatal D2/3R availability.

Study design:

Observational (follow-up) study.

Study population:

19 pre-menopausal Caucasian women that previously participated in our study "The

pleiotropic metabolic effects of bariatric surgery" and underwent Roux-en-Y gastric bypass surgery at least 1 year ago.

Main study parameters/endpoints:

1. Changes in striatal D2/D3 receptor availability more than 1 year after bariatric surgery in a weight stable phase as compared to pre-operative measurements;

2. Comparison of glucoregulatory hormones as well as regulating hormones and metabolites involved in appetite regulation, before versus 1 year after surgery, and in relation to changes in striatal D2/3 R availability;

3. Behavioral changes, before versus at least 1 year after bariatric surgery in a weight stable phase.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Subjects will visit the research centre once. The amount of blood withdrawn does not expose the participant to any medical risk. The exposure to radiation during SPECT scans is considered to be intermediate. The same questionnaires and behavioural tasks were performed by the subjects in the previous study and are not expected to cause any psychological discomfort.

Study objective

N/A

Study design

This follow-up study will take place at one time point. The acquired data will be compared to the data acquired in the same patients in our previous study 'The pleiotropic effects of bariatric surgery' (MEC 08/161).

Intervention

N/A

Contacts

Public
Academisch Medisch Centrum
Afdeling Nucleaire Geneeskunde F2-232
Meibergdreef 9
E.M. Zwaal, van der
Amsterdam 1105 AZ
The Netherlands
Scientific
Academisch Medisch Centrum
Afdeling Nucleaire Geneeskunde F2-232
Meibergdreef 9
E.M. Zwaal, van der
Amsterdam 1105 AZ
The Netherlands

Eligibility criteria

Inclusion criteria

Pre-menopausal Caucasian women that took part in our previous study "The pleiotropic effects of bariatric surgery" and underwent bariatric surgery > 1 year ago.

Exclusion criteria

1. Use of medication which interferes with dopamine metabolism;

2. Claustrophobia;

3. Pregnancy;

4. Tobacco use (i.e. smokers);

5. Unwilling or unable to provide informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2012
Enrollment:	19
Type:	Actual

Ethics review

Positive opinion

Date:	04-11-2012
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	NL3522
NTR-old	NTR3684

Register	ID
Other	METC AMC : 2012_332
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A