Long-term effects of bariatric surgery.

Gepubliceerd: 04-11-2012 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON29394

Bron
Nationaal Trial Register

Aandoening

obesity
metabolic syndrome
bariatric surgery
dopamine receptors

obesitas
metabool syndroom
bariatrische chirurgie
dopamine receptoren

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Overige ondersteuning: (volgt)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Striatal dopamine D2/3 receptor availability.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2012
Aantal proefpersonen:	19
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-11-2012
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	NL3522
NTR-old	NTR3684
Ander register	METC AMC : 2012_332
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A