Carotid intima-media thickness before and after bariatric surgery

Published: 30-03-2011
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Decrease of carotid intima media thickness after bariatric surgery as marker of reduction of cardiovasculair disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON36187

Source
ToetsingOnline

Brief title
CIMT and bariatric surgery

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
fatness, Obesity

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bariatric surgery, Carotid intima-media thickness, Premature atherosclerosis

Outcome measures

Primary outcome

Reduction of carotid intima-media thickness after bariatric surgery.

Secondary outcome

- Reduction of visceral fat mass after bariatric surgery

- Anthropometric measurements and bloodpressure before and after bariatric surgery

- Glucose, lipids and cholesterol profile before and after bariatric surgery

- Differences between the measurements and the three different types of bariatric surgery.

Study description

Background summary

Obesity is associated with cardiovascular morbidity and mortality. Carotid intima media thickness and viceral fat mass are prognostic indicators for premature atherosclerosis and indicative for the development of cardiovascular disease. Carotid intima media thickness is a accedive atherosclerotic parameter and the measurement is easily done and non invasive.

Study objective

Decrease of carotid intima media thickness after bariatric surgery as marker of reduction of cardiovasculair disease.

Study design

Observational study

Study burden and risks

Low

Contacts

Public
Maasstadziekenhuis

Groene Hilledijk 315
3075 EA Rotterdam
NL
Scientific
Maasstadziekenhuis

Groene Hilledijk 315
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age between 18 en 60 years
BMI > 40 kg/m2 or BMI > 35 kg/m2 with co-morbidity (DM, cardiac or lung problems, joint complaints)
Several registrated efforts of weightloss, guarded by a dietician

Exclusion criteria

Leeftijd < 18 en > 60 jaar
Personality disorderd / alcohol- and drugsabuse
< 5 years of adiposity
No serious attempts of weightloss
Obesity caused by hormonal or metabolic disorders, no willingness for analysis of such disorders or lifelong check-ups
Change in medication to prevent atherosclerosis (statins).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2011
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL35522.101.11