Extended metabolic phenotyping of subjects undergoing bariatric surgery

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

Summary

ID

NL-OMON36449

Source
ToetsingOnline

Brief title
Metabolic phenotyping bariatric patients

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal therapeutic procedures
- Vascular hypertensive disorders

Synonym
'obesity'; 'overweight'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Intervention

Keyword: Bariatric surgery, Insulin resistance, Metabolic syndrome X, Obesity

Outcome measures

Primary outcome

Predictive value of pre-operative variables to weight loss expressed as percentage excess weight loss, reversal of metabolic complications of obesity, quality of life and postoperative complications; eating behavior and quality of life before and after bariatric surgery; pre-operative metabolic variables in plasma and tissue (adipose tissue and liver) correlated with metabolic health c.q. markers of the metabolic syndrome

Secondary outcome

Prevalence of hypertension and metabolic complications of obesity before and after bariatric surgery; association of eating behavior with polymorphisms involved in appetite regulation and markers of pre-operative metabolic health.

Study description

Background summary

Bariatric surgery is the only proven treatment for obesity in the long term, however postoperative complications do occur. It is currently unknown which subgroup of patients will benefit the most in terms of weight loss and reversal of metabolic complications of obesity and which parameters will predict postoperative complications and treatment failure.

Study objective

To identify predictive variables correlated with percentage excess weight loss, reversal of metabolic complications of obesity and quality of life and postoperative complications; to identify metabolic variables correlated with markers of the metabolic syndrome. To assess the prevalence of hypertension and

metabolic complications of obesity in patients up for bariatric surgery. To study the association of eating behavior with possible polymorphisms in appetite regulation and with markers of metabolic health.

Study design

Prospective longitudinal cohort study

Study burden and risks

Blood and urine samples will be collected after an overnight fast four times: before, immediately prior to and 6 and 12 months after bariatric surgery. Biometric data such as waist circumference, BMI and blood pressure will also be measured. Subjects will be asked to fill in questionnaires regarding eating behavior (Dutch Eating Behaviour Questionnaire) and quality of life (SF-36). During surgery biopsies will be taken from visceral and abdominal subcutaneous adipose tissue and the liver. The risks of bleeding from the biopsy sites during the bariatric surgery procedure are very small because the biopsy sites are completely visible to the surgeon and local hemostasis will be checked.

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

Scheduled for malabsorptive bariatric surgery in one of the participating centers
Aged 18-65 years
Stable weight for 3 months prior to inclusion

Exclusion criteria

Major bleeding disorder
Renal insufficiency (creatinine > 150 umol/L), liver enzymes > 3x ULN
Unable to read or speak the Dutch language

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):	01-04-2011
Enrollment:	1200
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

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	NL35026.018.11