Determinants of weight loss after bariatric surgery

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To evaluate phenotypic, genetic, behavioural and environmental characteristics of patients after bariatric surgery and find predictors of response to bariatric surgery. In addition, to compare changes in cardiorespiratory fitness, fat free mass and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55139

Source
ToetsingOnline

Brief title
Determinants of weight loss after bariatric surgery

Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Nederlandse Obesitas Kliniek
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Bariatric surgery, GWAS, Metabolic health, Obesity

Outcome measures

Primary outcome

The main study endpoint is to evaluate phenotypic, genetic, behavioural and environmental characteristics of the included patients.

Secondary outcome

The secondary study endpoint is the difference in cardiorespiratory fitness and FFM and the relationship of these measurements and muscle function with weight loss and metabolic health after bariatric surgery. Therefore, the following additional parameters will be collected before and after surgery:

1. FFM

2. VO2 max

3. Isometric handgrip strength test

Study description

Background summary

Obesity is a major public health issue and is associated with several medical conditions. Excess body weight leads to variable levels of cardiovascular, pulmonary and skeletal muscle dysfunction resulting in poor cardiorespiratory fitness. The complexity of the multicausal nature of obesity makes treatment of this chronic disease difficult. Surgery has proven to be the most effective treatment for morbid obesity. However, weight loss results vary greatly between patients and it is unclear what the differences (genetic and metabolic) are between patients with the highest and patients with the lowest weight loss after surgery. This study is part of the international, multicentre study: SOPHIA. The objective of SOPHIA is to optimize treatment outcome of obesity. Patients will be selected based on the response to treatment (percentage total weight loss %TWL) 1-2 years after bariatric surgery. The aim of the study is to

compare outcomes and genetic characteristics of patients after surgery.

Study objective

To evaluate phenotypic, genetic, behavioural and environmental characteristics of patients after bariatric surgery and find predictors of response to bariatric surgery. In addition, to compare changes in cardiorespiratory fitness, fat free mass and metabolic status after bariatric surgery and to evaluate the relationships of cardiorespiratory fitness and muscle function with weight loss and metabolic health.

Study design

The SOPHIA project is an international, multicentre project. The current study is part of a cross-sectional study

Study burden and risks

Patients will be invited to visit the clinic for measurements and drawing of blood. Patients will have an additional of 15mL of blood drawn for GWAS analyses The visit will take 25 minutes. If the visit is more than 6 months before the scheduled annual follow up visit, this will be an extra visit to the NOK for the study purpose. Patient will be informed about this.
GWAS analysis might discover unexpected findings that may effect a patient's health.

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

- Patient is *18 and <75 years old
- Patient is treated at the NOK
- Patient has undergone a primary bariatric procedure
- Patient has at least 18 months of follow-up data and the following essential parameters are available: weight, BMI, gender and age

Exclusion criteria

Patients who do not understand the patient information letter will be excluded from participation in this study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2021
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2021
Application type:	Amendment
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

ID: 27224
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	NL 8865
CCMO	NL75166.018.20
OMON	NL-OMON27224