Determinants of weight loss after bariatric surgery

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

Samenvatting

ID

NL-OMON27224

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Morbid Obesity

Ondersteuning

Primaire sponsor: Nederlandse Obesitas Kliniek
Overige ondersteuning: Medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary Objective:
To evaluate phenotypic, genetic, behavioural and environmental characteristics of patients

after bariatric surgery and find predictors of response to bariatric surgery. This study is part of a large international study, called the SOPHIA study.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Obesity is a major public health issue and is associated with several medical conditions including diabetes type 2, cardiovascular disease and cancer. Excess body weight also 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 which variables explain the differences between patients with the highest and with the lowest weight loss after surgery. This study is part of the international (European), multicentre study: SOPHIA.
Objective: The overall objective of SOPHIA is to optimize treatment outcome of obesity. We will assess phenotypic, genotypic and behavioural predictors of weight loss after bariatric surgery. In addition, we will compare changes in cardiorespiratory fitness, fat free mass (FFM) and metabolic status and evaluate the relationships of cardiorespiratory fitness and muscle function with weight loss and metabolic health.
Study design: The SOPHIA project is an international (European), multicentre project. The current study is part of a cross-sectional study.
Study population: For this study, we will include patients who underwent primary bariatric surgery and have a minimal follow-up of 18 months. Blood samples will be drawn during the scheduled annual medical check after bariatric surgery. In addition to the standardized items that are part of the annual check-up, blood will be drawn for GWAS analyses. A total of 1000 patients will be included .
Main study parameters/endpoints: The main study endpoint is a prediction model including metabolic, anthropometric, genetic and behavioural characteristics to predict post bariatric surgery weight loss.
Secondary study endpoints are the difference in cardiorespiratory fitness and FFM and the relationship of these measurements with weight loss and metabolic health after bariatric surgery.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be invited to visit the clinic for measurements and drawing of blood during their scheduled annual medical post-bariatric surgery visit. Patients will have an additional of 15mL of blood drawn for GWAS analyses. Since the study measurements are combined with normal follow-up, no extra risk or burden is expected except for a longer duration of the visit.

Doel van het onderzoek

This study is part of the international, multicentre research project: SOPHIA (Stratification of

Obese Phenotypes to Optimize Future Obesity Therapy). The objective of SOPHIA is to optimize treatment outcome of obesity by identifying subpopulations of persons living with obesity in terms of the response to treatment of obesity and the risk of complications of obesity itself. To achieve this, the first step is to create an international database on treatment outcomes in patients with obesity. This database will include patients undergoing different types of treatment for obesity. Our cohort will only include patients who have undergone bariatric surgery.

Onderzoeksopzet

At a scheduled appointment anthropometric measurements will be completed by the researcher. As well, blood samples will be drawn for annual medical health checks, which is a standard part of the regular postoperative follow-up at NOK. There will be one extra blood sample for the GWAS analyses. In addition data will be collected from the electronic patient record . This data will be collected up to the moment that the patient is included in the study, for example, if a patients is included at 4 years follow-up, all data including the 4 year follow-up data will be used for study purposes

Contactpersonen

Publiek

Amsterdam Universitair Medische Centra
Rieneke van der Meer

+31 653148089

Wetenschappelijk

Amsterdam Universitair Medische Centra
Rieneke van der Meer

+31 653148089

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following

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 Patients can be included up to 5 years after surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
● Patients who do not understand the patient information letter will be excluded from participation in this study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	02-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55139
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8865
CCMO	NL75166.018.20
OMON	NL-OMON55139

Resultaten