

Preoperative predictors of weight loss and improved metabolic health after bariatric surgery

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This study is part of the international, multicentre European research project: SOPHIA (Stratification of Obese Phenotypes to Optimize Future Obesity Therapy). The overall objective of SOPHIA is to optimize treatment outcomes of obesity. We will...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29250

Bron

NTR

Verkorte titel

TBA

Aandoening

Obesity

Ondersteuning

Primaire sponsor: Nederlandse Obesitas Kliniek

Overige ondersteuning: Medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To validate biomarkers of response to bariatric surgery and to develop algorithms, which combine these variables, to predict individual responses.

Toelichting onderzoek

Achtergrond van het onderzoek

Obesity is the result of a complex interplay between genetics and epigenetics predisposition, environment, nutrition and psychology. It is a debilitating disease and a risk factor for the development of metabolic disorders such as dyslipidaemia, hypertension and hyperglycaemia. Surgery has proven to be the most effective treatment for morbid obesity with established positive long-term results of weight loss, remission of comorbid conditions and the improvement of Quality of Life (QoL). However, variability in these results after bariatric surgery is well known. Identifying preoperative predictors of weight loss and metabolic health is of clinical priority. Predictors could help further improve the quality of care for obesity by tailoring treatment to the individual, based on their predicted response and therefore optimize outcome after bariatric surgery. This study is part of the international, multicentre European research project: SOPHIA.

Doel van het onderzoek

This study is part of the international, multicentre European research project: SOPHIA (Stratification of Obese Phenotypes to Optimize Future Obesity Therapy). The overall objective of SOPHIA is to optimize treatment outcomes of obesity. We will validate the treatment response and clinical utility of identified biomarkers of response to bariatric surgery, discovered in obesity intervention studies (NL75166.018.20, NTR NL8865), in a population who undergoes surgical treatment. Furthermore, we will evaluate eligibility of biological and hormonal markers as predictors of weight loss and improvement of metabolic health and QOL after bariatric surgery.

Onderzoeksopzet

presurgery and postsurgery timepoints: 3 -12- 18- 60 months

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Ability to provide informed consent
- Patient is ≥ 18 and ≤ 75 years old
- BMI ≥ 40 kg/m² or ≥ 35 kg/m² with obesity related comorbidity
- Scheduled for primary bariatric procedure: Roux-en-Y gastric bypass or Sleeve Gastrectomy
- Stable weight 3 months prior to inclusion weight ($<10\%$ change in body weight for 3 months prior to assessments)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who do not understand the patient information letter
- Coagulation disorders
- Type 1 diabetes
- Severe liver disease
- Renal dysfunction
- Pregnancy anticipated in the first two years following surgery
- Use of antibiotics in last 6 months prior to inclusion
- Use of probiotics in last 6 months prior to inclusion

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	1299
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

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	NL9447
Ander register	METC AMC : 77692

Resultaten