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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29250

Source
NTR

Brief title
TBA

Health condition

Obesity

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- To determine if psychological factors (depression, anxiety, binge eating, eating behavior, food craving, body image, compliance to follow-up) are associated with genetic predisposition and to study how these psychological factors are associated with weight loss, metabolic health and improvement of QoL after bariatric surgery;
- To study the difference in cardiorespiratory fitness, muscle strength and physical activity and the relationship of these measurements with weight loss, metabolic health and QoL after bariatric surgery;
- To establish predictive (bio)markers of long-term outcomes after bariatric surgery (5-year follow-up).

In a subgroup of 40 patients, we have additional secondary objectives:
- To examine the change of gut hormones and inflammatory markers between 0-3 months after surgery and to evaluate the predictive value of these changes for weight loss and metabolic health 12 months after surgery.

Study description

Background summary

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.

Study objective

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.

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

● 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)

Exclusion criteria

● 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	1299
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9447
Other	METC AMC : 77692

Study results