The immune system and microbial tone in relation to NAFLD/NASH before and after BARIatric surgery in the morbidly obese in Amsterdam; the BARIA cohort study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22589

Source
Nationaal Trial Register

Brief title
BARIA

Health condition

obesity
nafld-nash
bariatric surgery

Sponsors and support

Primary sponsor: amc
Source(s) of monetary or material Support: amc

Intervention

Outcome measures

Primary outcome

To identify microbial, immunological and metabolic markers associated with weightloss after bariatric surgery. To this end, we will collect before, during surgery and after 2 years follow up.

Secondary outcome

To apply systems biology approach to identify hierarchy of driving mechanisms (microbial, immunological and metabolic markers) in relation to diet and satiety involved in the long term beneficial weight loss effects of bariatric surgery that can be used for personalised medicine

Study description

Study objective

It is increasingly recognized that the immune system is a major player in this obesity related disease and the switch from benign to malign (insulin resistance and DM2) obesity is associated with changes in the immune system . In this regard, animal studies have suggested that the intestinal microbiome is thought to play a major role in driving these immunological and metabolites changes. However, at this moment it is unknown whether and to what extend intestinal microbiota and immunological tone can predict metabolic response (improvement in insulin sensitivity and weightloss) upon bariatric surgery. Increased understanding of the pathophysiological mechanism as well as their relationship to metabolic disturbances are thought to be of crucial importance to discover new diagnostic and therapeutical targets in obesity associated insulin resistance and NAFLD/NASH. Moreover, this study will identify the underlying pathophysiological mechanisms in subjects that will have NAFLD/NASH reduction upon the surgery (responders) and those that have no beneficial effect on at all (non-responders). This might help to predict who will benefit from the surgical intervention and in whom this is not effective.

Study design

0,1,2,12 and 24 months

Intervention

bariatric surgery

Contacts

Public
AFDELING INWENDIGE GENEESKUNDE AMC
MEIBERGDREEF 9, KAMER F4.159.2
M. Nieuwdorp
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666612
Scientific
AFDELING INWENDIGE GENEESKUNDE AMC
MEIBERGDREEF 9, KAMER F4.159.2
M. Nieuwdorp
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666612

Eligibility criteria

Inclusion criteria

- Scheduled for bariatric surgery

- Ability to provide informed consent

- No more than 5% weight loss in 6 months prior to surgery

- No more than 3% weight loss in 1 month prior to surgery

Exclusion criteria

- Known genetic basis for insulin resistance or glucose intolerance

- All medical and psychiatric conditions except for obesity related diseases.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2016
Enrollment:	1500
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-07-2016
Application type:	First submission

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	NL5837
NTR-old	NTR5992

Register	ID
Other	: METC 2015_357

Study results