Obesity, Bariatric Surgery, Gut Microbiome and Immunity Changes

Published: 13-04-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52532

Source
ToetsingOnline

Brief title
OBAMA

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
gut microbiome, Immune system changes

Health condition

Immuunsysteem : veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Medtronic ,Medtronic B.V.

Intervention

Keyword: Immunity, Microbiome, Obesity, Telomeres

Outcome measures

Primary outcome

The main endpoint of this study is to determine whether morbid obesity induces premature T cell aging in circulation T cells and whether bariatric surgery halts or reverses obesity-induced effects on T cells (longitudinal setup with follow-up at 3, 6,12 and 18 months postoperative).

Secondary outcome

- To determine whether obesity-induced premature T cell aging is also present in adipose tissue, muscle tissue and liver tissue obtained during bariatric surgery.

- To determine whether the function of the immune system changes after bariatric surgery.

- To determine whether the gut microbiome changes after bariatric surgery and to compare the change in the gut microbiome to obese individuals not undergoing bariatric surgery but participating in compared lifestyle intervention.

Study description

Background summary

Individuals with morbid obesity have a shorter life expectancy than individuals with a healthy weight. Morbid obesity is also linked with changes in the immune system, which can be reversed after bariatric surgery. Multiple studies have shown that the accelerated aging process that is found in individuals with morbid obesity can be a possible explanation for this. The aging process is investigated by the determinatin of telomeres (protecting ends of DNA). The shorter the telomeres, the older the individual. Individuals with a short telomere have a higher risk for the development of cancer. At this moment, the telomere lengt is determined based on leukocytes. With this study, we want to determine whether the telomere length in leukocytes is comparable to that in liver tissue, fat tissue en muscle tissue.

Both obesity and aging are accompanied by changes in the gut microbiome. Studies to the gut microbiome have shone that morbid obese individuals have a different gut microbiome than healthy individuals. Most of the studies have been performed in mice. In our study, we will investigate whether weight loss, either with or without bariatric surgery, influences the gut microbiome.

Study objective

To investigate of the accelerated aging process in morbid obese individuals can be stopped or reversed by bariatric surgery. We also want to investigate whether the aging process in muscle tissue, liver tissue and fat tissue is comparable to the aging process in leukocytes. Also, we want to investigate whether the immunesystem changes after bariatric surgery. We also want to investigate whether excessive weight loss, either with or without bariatric surgery, influences the gut microbiome.

Study design

The study design of our study is a prospective cohort study.

Study burden and risks

A possible adverse event is bleeding after liver, muscle or adipose tissue biopsy. To minimize the possible unfavourable outcome, these biopsies will be done at the beginning of the procedure. The surgeon will have a clear view of the location of the biopsy during the complete procedure and will have the maximal amount of time to anticipate on a bleeding when it occurs.

There will be no extra visits to the outpatient clinic if patients participate

in our study. After 3 months, an extra vena puncture with 4 blood samples of 6 mL will be performed to determine the telomeres in the blood. Also, at 3 other follow-up moments 4 extra blood samples of 6 mL will be taken next to the standard blood samples at 6, 12 and 24 months postoperative.

Patients will be asked to fill out 2 questionnaires at five follow-up points which will each take 10 minutes extra time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18 - 65 years
- Body Mass Index >= 35 with the presence of severe comorbidity related to morbid obesity (diabetes mellitus type 2, obstructive sleep apnoea syndrome (OSAS), hypertension, etc.) or a BMI >= 40 with or without the presence of

severe comorbidity related to morbid obesity

Exclusion criteria

- Morbid obesity caused by genetic defects or syndromes
- Perioperative conversion to an open approach

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2018
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2018

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL64570.101.17