Jejunum ex vivo

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The aim of the current study is to determine the transport functionality, integrity, and viability in intestinal tissue obtained from patients who are expected to have a disturbed intestianl functionality due to severe obesity.

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

Summary

ID

NL-OMON56681

Source
ToetsingOnline

Brief title
JEJUNEX

Condition

- Other condition

Synonym
Intestinal functionality and health, intestinal health

Health condition

Onderzoek naar de functionaliteit en gezondheid van de dunne darm in mensen met obesitas.

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: TNO

Intervention

Keyword: Intestinal health, Obesity

Outcome measures

Primary outcome

The primary endpoint of this study is to determine transport functionality, integrity, and viability in each intestinal biopsy. The transport functionality is shown as the ratio of transcellular to paracellular transport, also called the Papp ratio (Papp = Apparent permeability rate). Permeability of FITC-Dextran (4000 Dalton, FD4) determines intestinal integrity, and secretion of lactate dehydrogenase (LDH) determines tissue viability.

Secondary outcome

In addition to these primary endpoints, processes that play an important role in intestinal and overall health will also be measured in each biopsy. This includes: 1) absorption and metabolism of foods and medicines, 2) (influencing) intestinal permeability, 3) release of satiety hormones, 4) local immunological reactions, and 5) interaction with the intestinal microbiome.

Study description

Background summary

Gut health has a major impact on human health. Processes that play an important role in intestinal health are: 1) 1) absorption and metabolism of foods and medicines, 2) (influencing) intestinal permeability, 3) release of satiety hormones, 4) immunological reactions, and 5) interaction with the intestinal microbiome. Most of these processes occur throughout the small and large intestines, but the interaction with the microbiome is particularly important in the large intestine. In addition to ingredients and medicines, people are also orally exposed to various types of contaminants (e.g. microplastics),

which may have a negative effect. Understanding and investigating of these processes in healthy and dysfunctional intestines is therefore of great importance. For example, it can be used to test ingredients that contribute to better intestinal health, for example in people with intestinal disorders. Possible results may also contribute to adjusting drug dosages for patients in a clinical setting. In addition, certain side effects caused, for example, by drug-drug or drug-food interactions can be prevented.

Study objective

The aim of the current study is to determine the transport functionality, integrity, and viability in intestinal tissue obtained from patients who are expected to have a disturbed intestianl functionality due to severe obesity.

Study design

This is a cross-sectional cohort study in which patients undergo a Roux-en-Y gastric bypass surgery. A biopsy of the jejunum will be collected during the operation.

Study burden and risks

Previous research (BARICO study) has shown that the collection of a jejunum biopsy does not entail any additional risks. Furthermore, there will be no burden for the patients, as they do not have to undergo additional study procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients with the age of 18 or older
- BMI > 40 kg/m2
- BMI > 35 en < 40, with a obesity related comorbidity of which is suspected that it improves after surgery induced weight loss.

Exclusion criteria

no exlcusion criteria

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024

Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO Date:	09-04-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-06-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86051.091.23