

# 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 intestinal functionality due to severe obesity.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 intestinal 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**

### **Public**

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### **Scientific**

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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/m<sup>2</sup>
- BMI > 35 en < 40, with a obesity related comorbidity of which is suspected that it improves after surgery induced weight loss.

### Exclusion criteria

no exclusion 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