

# Effect of the BaroSense ACE Stapler procedure on food intake, food-reward, gastric emptying, hormone release, inflammatory profile, gut microbiota and behaviour towards food.

Published: 27-06-2012

Last updated: 26-04-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal therapeutic procedures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON37637

### Source

ToetsingOnline

### Brief title

BaroSense ACE Stapler Sub-study

### Condition

- Gastrointestinal therapeutic procedures

### Synonym

extreme overweight, obesity

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** BaroSense Inc.,bedrijf

## Intervention

**Keyword:** effectivity, endoluminal bariatric surgery, mechanism, obesity

## Outcome measures

### Primary outcome

To assess the effect of the BaroSense ACE Stapler on satiety, satiation, food intake and hunger.

### Secondary outcome

- To investigate the effect of stomach tissue ligation by the ACE Stapler on gastro-intestinal hormone release (CCK, GLP-1, PYY, Ghrelin and Leptin)
- To asses the effect of stomach tissue ligation by the ACE Stapler on gastric volume and gastric emptying rate (by real time MRI and 13C octanoic acid breath test)
- To asses the effect of stomach tissue ligation by the ACE Stapler on ad libitum meal intake and post-prandial satiety
- To investigate the effect of stomach tissue ligation by the ACE Stapler on several inflammatory markers
- To compare the gastric emptying time of the MRI with the 13C octanoic acid breath test
- To investigate the effect of stomach tissue ligation by the ACE Stapler on food-reward
- To investigate the effect of stomach tissue ligation by the ACE Stapler

behaviour towards food

- To investigate the effect on expression and localisation of nutrient

receptors in the stomach and duodenum

## Study description

### Background summary

Obesity and its associated conditions have reached epidemic proportions. Estimates are that about one third of the adults in the United States are obese. At this moment there are many therapeutic approaches for the treatment of obesity. But, efficacy of most treatment options are limited and so far surgical intervention has been proven to be the only strategy to overcome severe obesity. However, although bariatric surgery is the most important treatment strategy at this moment, it had limitations and risks. Non-incisional endoscopic procedures could minimize these limitations and risks.

BaroSense developed a new device, called the Articulating Circular Endoscopic (ACE) Stapler, which can be used in the treatment of obesity. It's a trans-oral procedure, which intends to reduce the ability of the stomach to expand by creating plications in the region of the fundus and the antrum. In contrast with other bariatric surgery it is endoscopically performed, reversible and if it fails most future surgical options are still open.

The main study (\*Open, prospective study to evaluate the safety and preliminary effectiveness of the BaroSense ACE\* Stapler for the treatment of obesity\*, multicenter study (MUMC+ and AMC), accepted by METC AMC) seeks to determine the safety and efficacy of this plicating system for patients with severe obesity.

### Study objective

In this sub-study we want to unravel the exact mechanism and provide more information about the efficacy of the BaroSense ACE\* Stapler. Therefore we will measure changes in various parameters that are known to affect weight loss and metabolism, before and after gastric plication (by using the BaroSense ACE\* Stapler) in overweight subjects (these parameters will only be measured at patients in MUMC+). These parameters are post-prandial satiety, food-reward, gastric emptying, food intake, satiety hormone release, behaviour towards food, gut microbiota composition and inflammatory markers.

### Study design

The mechanisms will be studied by two additional test days before, and two additional test days after the procedure. We will be doing an MRI scan of the

stomach before and after the procedure and a meal tolerance test, also before and after the procedure. The MRI scan will provide information on volume change, accommodation and emptying of the stomach. During the meal tolerance test we will collect blood samples, breath samples and VAS questionnaires before and after a standardized meal.

Optionally, a fMRI of the brain will be conducted during the meal tolerance test to assess food-reward and whether food-reward is influenced by the procedure.

### **Study burden and risks**

The additional risk of the substudy consists of two times two additional days which will be spent at the hospital. There is hardly any additional risk. The MRI scan is free of radiation and there's only an increased risk of hematoma after collecting blood through the intravenous catheter instead of venapuncture. Additional risk of bleeding due to the biopsy of duodenal and gastric tissue is very low.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patient is included in the main BaroSense ACE Stapler study.

### Exclusion criteria

presence of contra-indications for MRI

claustrophobia

pregnancy

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-07-2012

Enrollment: 15

Type: Actual

## Ethics review

Approved WMO

Date:	27-06-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	03-06-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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	NL39402.068.12