Gastric Emptying measured with MRI and Scintigraphy in patients with successful versus unsuccessful weight loss after Sleeve gastrectomy

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To assess gastric emptying (GE) with MRI in patients with successful versus unsuccessful weight loss after gastric sleeve surgery and compare with gastric emptying as measured with the more frequently used scintigraphy.

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

Summary

ID

NL-OMON49419

Source
ToetsingOnline

Brief title
EMRISS

Condition

- Other condition

Synonym
Bariatisc surgery; obesity

Health condition

Bariatrische chirurgie; maagontlediging; obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Eigen middelen

Intervention

Keyword: Gastic emptying, Gastric sleeve, MRI, Scintigraphy

Outcome measures

Primary outcome

Primary objectives:

1. To compare gastric emptying rate between patients with successful and unsuccessful weight loss two years after sleeve gastrectomy.

2. To compare gastric emptying rate as measured with MRI to gastric emptying rate measured with scintigraphy

Secondary outcome

Secondary objectives:

1. To compare sleeve characteristics between patients with successful and unsuccessful weight loss

2. Assess the association between gastric emptying rate and gastric sleeve characteristics in each group.

3. To compare subjective ratings of gastric fullness and wellbeing between patients with successful and unsuccessful weight loss.

Study description

Background summary

Sleeve gastrectomy (SG) increases gastrointestinal motility, which influences feelings of fullness and satiety. Patients* weight loss response on SG varies widely and is difficult to predict. By understanding the differences in gastric emptying (GE) between patients with sufficient weight loss (Total weight loss (TWL) > 35%) and insufficient weight loss (TWL <25%), we may obtain better insight in the aetiology of weight loss after sleeve gastrectomy. We will measure GE with scintigraphy and MRI. MRI is a non-invasive imaging method which provides more detailed images of the SG compared to the conventionally used scintigraphy scans.

Study objective

To assess gastric emptying (GE) with MRI in patients with successful versus unsuccessful weight loss after gastric sleeve surgery and compare with gastric emptying as measured with the more frequently used scintigraphy.

Study design

A cross-sectional observational study in which GE rate, gastric sleeve width, gastric sleeve outlet diameter and gastric motility are measured during two study visits, one visit GE is measured with MRI and the other visit with scintigraphy, in patients with successful versus unsuccessful weight loss two to three years after gastric sleeve surgery.

Study burden and risks

Patients will be asked to undergo both a MRI and gastric scintigraphy session within a four week period, after a minimum of 4 hours fasting. Patients undergo a 60-min MRI and gastric scintigraphy scanning session after ingestion of 125 gram of a semi-solid food. Imaging measurements will be performed at baseline and every 10 min after ingestion up to t=60 minutes. After each measurement participants will rate fullness, bloating, satiety and wellbeing. These measurements are non-invasive and carry minimal risk. The study is non-therapeutic.

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

- Women aged between 20 and 55 years who underwent sleeve gastrectomy as primary procedure with either TWL < 25% or TWL > 35%.
- Patients who had a follow-up period of 2-3 years after sleeve gastrectomy

Exclusion criteria

- Maximum BMI >50 kg/m2
- Patients with a disease known to affect appetite, gastric emptying or gastrointestinal motility
- Patients who are unable to stop medications that affect gastric emptying and/or motility prior to measurements. It is depending on t1/2 for how long they need to stop medication.
- Patients who started menopause
- Patients with gastrointestinal problems or, gastric or intestinal diseases
- Patients with a drug or alcohol addiction
- Patients who are unable to stop smoking for 24 hours
- Patients who are pregnant or lactating
- Patients who have an intolerance or allergy for one of the components of the test product
- Patients who have a contra-indication to MRI scanning

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2022
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-01-2021
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	NL74432.091.20