ASSESSMENT OF POUCH EMPTYING WITH MRI AFTER ROUX-EN-Y GASTRIC BYPASS SURGERY

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To assess PE rate and pouch characteristics in good and bad responders two years after LRYGB by MRI.

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

Summary

ID

NL-OMON46057

Source
ToetsingOnline

Brief title
Pouch emptying after RYGB

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
bariatric surgery, gastric bypass surgery

Health condition

obesitas, bariatrische chirurgie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: gastric / pouch emptying, gastric bypass (RYGB), obesity

Outcome measures

Primary outcome

Primary: PE rate two years after LRYGB, pouch characteristics; extended pouch

width and pouch outlet diameter.

Secondary outcome

Secondary: subjective ratings of fullness and wellbeing.

Study description

Background summary

One of the most performed type of bariatric surgery in the Netherlands is the Laparoscopic Roux-en-Y Gastric Bypass (LRYGB). However, LRYGB is not effective in all bariatric patients, around 10% to 15% of bariatric patients have insignificant WL. The exact physiological mechanisms behind this individual variation are unknown. In several studies, the pouch emptying (PE) rate has been suggested as an important factor related to the successfulness of WL after LRYGB.
However, studies regarding PE and WL showed contradictive results; one pilot study found that patients with poor WL (bad responders) showed greater PE, opposing to one study which showed greater PE in successful WL patients (good responders), and one study that showed normal PE in good responders and slower PE in bad responders. Thus, more research regarding the relation between PE and weight loss in LRYGB patients is needed.
PE rate can be measured with scintigraphy (SG). However, magnetic resonance imaging (MRI) does not use harmful gamma radiation and provides more detailed anatomical information, which can be useful to detect differences in PE rate but also pouch characteristics such as its diameter. Such characteristics may explain differences in PE rate.
We hypothesize that PE rate is greater in bad responders in terms of WL

compared to good responders after LRYGB. Additionally, we hypothesize that pouch characteristics, such as extended pouch width and pouch outlet diameter, differ between good and bad responders after LRYGB.

Study objective

To assess PE rate and pouch characteristics in good and bad responders two years after LRYGB by MRI.

Study design

A cross-sectional observational study in which PE rate, extended pouch width and pouch outlet diameter are measured with MRI in good and bad responders two years after LRYGB.

Study burden and risks

Patients will be asked to fast overnight and undergo a 90-min MRI scanning session after ingestion of 125 gram of a semi-solid food. They will also rate their fullness and wellbeing at baseline and after each gastric MRI scan. 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
- Patients must be able to adhere to the study visit schedule and protocol requirements
- Patients must be able to give informed consent (IC) prior to any study procedures
- Patients who had a follow-up period up until two years after LRYGB and have successful or unsuccessful weight loss.
- Willing to be informed about incidental findings of pathology and approving of reporting this to their general physician

Exclusion criteria

- Diabetes Mellitus
- Menopausal
- Gastrointestinal problems, gastric or intestinal diseases
- Drug or alcohol addiction
- Inability to stop smoking during the overnight fasting period
- Pregnant or lactating
- Having an intolerance or allergy for one of the components of the test product
- Inability to stop medications that affect gastrointestinal emptying like antisecretory drugs, narcotics and prokinetic agents
- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, prokinetics, theophylline, calcium blocking agents, opioids)
- Having a contra-indication to MRI scanning (including, but not limited to):
o Pacemakers and defibrillators
o Intraorbital or intraocular metallic fragments
o Ferromagnetic implants

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2019
Application type:	First submission
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
ClinicalTrials.gov	NCT02539641

Register	ID
CCMO	NL67969.091.18