The Gallbladder Function after Gastric Bypass Surgery - Trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40635

Source
ToetsingOnline

Brief title
The FUGA Trial

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
cholecystolithiasis, gallstones

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Wetenschapsfonds Maatschap Heelkunde Maasstadziekenhuis

Intervention

Keyword: Cholecystokinin, Gallbladder Function, Roux-en-Y Gastric Bypass, Ultrasonography

Outcome measures

Primary outcome

Ultrasonography measured gallbladder functions after RYGB. Gallbladder function

is assessed using the measurement of ejection fraction, residual volume and

fasting volume after an overnight fast.

Secondary outcome

Secondary study parameters/endpoints (if applicable)

1. Incidence of biliary symptoms

2. Incidence of bile sludge

3. Incidence of symptomatic cholecystolithiasis

4. Serum cholecystokinin levels

Other study parameters

Patient characteristics:

- Age

- Gender

- Ethnicity

- Comorbidities

- BMI

- Weight loss

- Excess weight loss

Study description

Background summary

Obesity is a growing problem with many adverse effects on human health. The Roux-en-Y Gastric Bypass has been an effective method to treat obesity. The long-term mortality decreases in the treated population. The incidence of gallbladder pathology is increasing after a RYGB procedure . Changes in cholesterol saturation of the bile, increased crystallizing factors, and a deterioration of the gall bladder function are likely to be the cause of this increase in gallbladder pathology. Several studies have been conducted on this subject, but several questions remain.

Study objective

Primary Objective: To assess the impact of RYGB on gallbladder function (during a follow-up interval of 1 year). We will assess the fasting volume, the ejection fraction and the residual volume of the gallbladder. In addition, we will compare serum cholecystokinin levels before and after RYGB.
Hypothesis: We expect that gallbladder function will decrease (decreased ejection fraction, increased residual volume and fasting volume) during follow-up after RYGB.

Secondary Objective(s):
1 To evaluate the number of patients that will develop sludge or gallstones after a RYGB
2 To determine in which time-frame most gallstones will develop
3 To assess if gallstones development is correlated with a change in gallbladder function
4 To assess if the amount of EWL correlates with a change gallbladder function
5 To define causes of impaired function, eg is this CCK mediated or is nervus vagus damage contributing.
6 To predict gallstone development in the RYGB patient population

Study design

An observational case-control study will be conducted at the Maasstad Hospital, Rotterdam. Patients will be included from the bariatric outpatient clinic during their intake visits. The gallbladder function of the subjects will be assessed two weeks prior to and 6 and 12 months after their RYGB. Together with the ultrasonographic assessment serum cholecystokinin levels will be determined. After 12 months of follow-up data collection will be completed and statistical analysis of the data will be conducted.

Study burden and risks

The burden on the subject is low. The ultrasound will take place in the morning so the fasting period will be an overnight fast. The test meal carries no risk. The venous puncture is common practice, which hardly involves any risks.

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

Eligible patients meet the current bariatric surgery criteria used in our clinic, in accordance with IFSO criteria.
The age of the patient is 18-65 years. BMI >= 40 kg/m2 or BMI >=35 kg/m2; with serious comorbidities related to obesity such as diabetes mellitus, OSAS and arthrosis.

Exclusion criteria

-Patients with previous (laparoscopic) cholecystectomy will be excluded.
-Patients with presenting with biliary symptoms or gallstones at time of RYGB will be excluded.
-Patients with a different intervention than a Roux-en-Y Gastric Bypass will be excluded (eg. Gastric sleeve, gastric band, etc.)
-Ursodeoxycholic acid usage.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL48439.101.14