ISRCTN15208502 https://doi.org/10.1186/ISRCTN15208502

Effect of sleeve gastrectomy on patients with or without preoperative gastroesophageal reflux disease

Submission date
24/03/2015

Recruitment status
No longer recruiting

Registration date
15/04/2015

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gastroesophageal reflux disease (GERD) is a common condition where stomach acids leak out into the oesophagus (gullet). Symptoms include heartburn, acid reflux (acid coming back up into the mouth), and difficulty and pain when swallowing. People who are overweight or obese are at high risk of developing GERD. In some cases, 24-hour pH monitoring is recommended to help diagnose the condition. This measures pH levels around the oesophagus to test for excess acid. Laparoscopic sleeve gastrectomy (LSG), where the stomach is made smaller to restrict the amount of food that can be eaten, has been found to work well in treating morbid (life-endangering) obesity based on both short and mid-term studies. However, there are concerns that LSG may lead to GERD or worsen existing GERD. There has not yet been any rigorous large studies investigating this using 24-hour pH monitoring. The aim of this study is to observe pH levels in the oesophagus in people having LSG using 24-hour pH monitoring.

Who can participate?
Adults who are obese and scheduled to have LSG surgery.

What does the study involve?
Each participant undergoes 24-hour pH monitoring just before they have their LSG surgery. Six months following surgery, they then have a usual full clinical and biological examination and are invited to undergo 24-h pH monitoring again to test for GORD.

What are the possible benefits and risks of participating?
Participants enjoy the benefit of a gold standard test to test for GERD in clinical practice. No major adverse outcomes have been reported with such a test.

Where is the study run from?
The University Nutrition Department at Ambroise Paré University Hospital, West Paris (France)

When is the study starting and how long is it expected to run for?
January 2012 to April 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Sébastien Czernichow

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of sleeve gastrectomy on patients with or without preoperative gastroesophageal reflux disease: a pH-metry based study

Study objectives
Gastroesophageal reflux disease is a frequent obesity-related co-morbidity which is objectively assessed by 24-h pH monitoring. Sleeve gastrectomy (LSG) has been found as an effective treatment for morbid obesity based on short and mid term studies. However, some concerns have been raised on LSG with the unpredictable risk of de novo or worsening GERD. Rigorous large studies using 24-h pH monitoring are lacking. The aim of our study was to assess post operative influence of sleeve gastrectomy (LSG) on GERD in obese morbid patients with or without preoperative GERD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Observational study

Study design
Patients scheduled for sleeve gastrectomy were offered to undergo 24-h pH monitoring in the preoperative time and 6 months after surgery.

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Grade 3 obesity

Interventions
Laparoscopic sleeve gastrectomy:
The aim of our study is to determine whether sleeve gastrectomy leads to de novo gastroesophageal reflux disease or exacerbates preoperative GERD in morbidly obese patients. Ambulatory esophageal pH monitoring is the gold standard for the diagnosis of gastroesophageal reflux disease. The nasoesophageal catheter was placed 5 cm above upper border of the lower esophageal sphincter. Esophageal pH monitoring was performed for 24 hours. There were recorded total, supine and upright time with esophageal pH<4. Patients were offered to undergo the 24-h pH monitoring preoperatively and 6 months after the bariatric procedure.

Intervention Type

Procedure/Surgery

Primary outcome measure
Percentage with esophageal pH<4 for total time ≥4.2%.

Secondary outcome measures
Percentage with esophageal pH<4 for upright and supine time ≥4.2%.

Overall study start date
01/01/2012

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Adults patients
2. Body Mass Index >35 kg/m²
3. Eligible for bariatric surgery
4. Preoperative medical management > 6 months
5. According to NIH/HAS criteria for bariatric surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Total final enrolment
89

Key exclusion criteria
1. Refusal
2. Huge Hiatal Hernia
3. History of hiatal surgery
4. Pregnancy

Date of first enrolment
01/07/2012

Date of final enrolment
15/09/2014

Locations

Countries of recruitment
France

Study participating centre
CHU Ambroise Paré
Boulogne-Billancourt
France
92100

Sponsor information

Organisation
CHU Ambroise Paré

Sponsor details
Avenue Charles de Gaulle
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03j6rvb05

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The results of the study will be published in a peer-reviewed scientific journals and presented at conferences (years 2015-2016)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	24/07/2020	Yes	No