



Clip Ascent and Sleeve Gastrectomy

CLINICALTRIALS.GOV IDENTIFIER
NCT03932968

RECRUITMENT STATUS
ACTIVE, NOT RECRUITING

FIRST POSTED
MAY 1, 2019

LAST UPDATE POSTED
MAY 1, 2019

STUDY DESCRIPTION

Brief Summary

This is a single institution study. All patients, one year after sleeve gastrectomy will be included. All will have a CT scan looking for clip ascent. For patients with chronic gastric symptoms such as retrosternal burning, regurgitations, and epigastric pain, a pH-metry will be performed. Those symptoms appeared at least 6 months after the surgery. A second consultation is done one year after. The aim of the study is to correlate clip ascent, pyrosis proved by ph-metry and epigastric symptoms after sleeve gastrectomy. The demographic data collection confirms the definition of clip ascent, define its frequency, and look for correlation with the median weight loss.

Condition or Disease: Sleeve Gastrectomy
Obesity

Intervention/treatment: Procedure: pH-metry during 24 hours

Phase: N/A

DETAILED DESCRIPTION

There is a strong association between gastric reflux and obesity. A severe reflux is a contraindication for a sleeve gastrectomy for some surgeons. However the impact of sleeve gastrectomy on reflux is not clear. A de novo reflux is described for 2 to 18% of patients and many patients have unclear epigastric symptoms. One of the cause could be clip ascent which could justify a second surgery. This is a single institution study. All patients, one year after sleeve gastrectomy will be included. All will have a CT scan looking for clip ascent. For patients with gastric symptoms such as retrosternal burning, regurgitations, and epigastric pain, a pH-metry will be performed. A second consultation is done one year after. The aim of the study is to correlate clip ascent, pyrosis proved by ph-metry and epigastric symptoms after sleeve gastrectomy. The demographic data collection, confirms the definition of clip ascent, define its frequency, and look for correlation with the median weight loss. A medical information note is given to every patient at the first consultation.

STUDY DESIGN

Study Type: Observational

Estimated Enrollment : 223 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: Observational Study of Epigastric Symptoms Chronicles, the Rise of the Line of Clips and Their Management in Obese Patients One Year Later Sleeve Gastrectomy

Actual Study Start Date: January 2017

Estimated Primary Completion Date: June 2019

Estimated Study Completion Date: December 2019

GROUPS AND COHORTS

Groups/Cohorts	Intervention/treatment
: Symptomatic pain For patients with gastric symptoms such as retrosternal burning, regurgitations, and epigastric pain, a pH-metry during 24 hours will be performed.	Procedure: pH-metry during 24 hours For patients with gastric symptoms such as retrosternal burning, regurgitations, and epigastric pain, a pH-metry will be performed

OUTCOME MEASURES

Primary Outcome Measures: 1. Measure of clip ascent [Time Frame: 12 months]

All patients at one year after a sleeve gastrectomy will be included. They will all have a CT scan and symptomatic patients will have a phmetry. Observational between epigastric symptoms, clip ascent at one year after a sleeve gastrectomy.

Secondary Outcome Measures:

1. Frequency of clip ascent [Time Frame: 18 months]

Clip ascent is noticed after sleeve surgery but data about it are unknown

2. Oesogastric reflux proved by phmetry [Time Frame: 12 months]

The frequency of oesogastric reflux proved by phmetry at 12 months after surgery is unknown

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- sleeve gastrectomy operated for at least 1 year

Exclusion Criteria:

- acute abdominal pain,

- epigastric pain occurring after the surgery (no 6 months delay),

- pregnant women

CONTACTS AND LOCATIONS

Contacts

Locations

France

Hopital Bichat

Paris

Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

Investigator

Principal Investigator : PASCALE KARILA-COHEN, Assistance Publique - Hôpitaux de Paris
MD

MORE INFORMATION

Responsible Party : Assistance Publique - Hôpitaux de Paris

ClinicalTrials.gov Identifier : NCT03932968

Other Study ID Numbers : NI17015J, 2017-A01608-45

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Last Verified : February 2019

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Assistance Publique - Hôpitaux de Paris: *oesogastric reflux*
sleeve gastrectomy clip ascent
sleeve gastrectomy follow-up