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Comparison of minimally invasive versus conventional laparoscopic (keyhole) bariatric surgery

Submission date 19/02/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/03/2021	**Overall study status** Completed	
Last Edited 05/07/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Laparoscopic Sleeve Gastrectomy (also called bariatric surgery) is the most performed bariatric surgery worldwide with 155,000 procedures in the United States in 2018 and 36,000 in France in 2016.
LSG surgery is done in a hospital under general anesthesia. The surgeon will make about five small cuts in the belly. He or she will do the surgery using a thin, long, telescope with a tiny camera at the end. Instruments pushed through the incisions will be used to remove about 80% of the stomach. The surgeon will do the procedure using images on a TV screen in the operating room.
This surgery takes out the part of the stomach that curves outward, called the fundus. After the fundus is taken out, the surgeon will close the rest of the stomach into a tube shape that looks like a banana or the sleeve of the shirt, hence the name "sleeve gastrectomy."
A recent systematic review demonstrated the safety and efficacity of single incision laparoscopic sleeve gastrectomy. But to our knowledge, no trial has compared traditional multiport sleeve gastrectomy to single incision laparoscopic sleeve gastrectomy. The aim of this study is to compare these two techniques and to determine the superiority of one of them considering the following aspects: postoperative pain, postoperative scars esthetic aspect, postoperative sex life along with postoperative diurnal and nocturnal quality of life.

Who can participate?
Adult patients with body mass index >40 kg/m² or with a body mass index >35 kg/m² with serious comorbidity such as obstructive sleep apnea, diabetes mellitus or hypertension undergoing laparoscopic sleeve gastrectomy as a primary bariatric procedure.

What does the study involve?
As participants undergoing sleeve gastrectomy (regardless of number of used ports) sign up for a scheduled postoperative follow-up, no additional outpatient visit or examination is required in this study.

What are the possible benefits and risks of participating?
This study is a non-randomized trial. Patients will be freely addressed to one of two teams of surgeons who adopted and routinely perform exclusively one of two surgical approaches (conventional laparoscopy or single-port laparoscopic sleeve gastrectomy). Therefore, no specific additional benefits and risks are expected from the participation of patients in the trial.

Where is the study run from?
Antoine Beclere Hospital of Assistance Publique-Hôpitaux de Paris (France)

When is the study starting and how long is it expected to run for?
January 2021 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Single incision laparoscopic sleeve gastrectomy versus conventional multiport sleeve gastrectomy (ONE SLEEVE): a prospective non-randomized controlled trial

Acronym
ONE SLEEVE

Study objectives
Single incision laparoscopic sleeve gastrectomy provides an improved postoperative outcome compared to conventional multiport sleeve gastrectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval is required for this study, since it is a nonrandomized controlled trial of a routine procedure. This was validated with the clinical research unit of the Paris-Sud University.

Study design
Single-centre prospective non-randomized controlled observational study

Primary study design
Observational

Secondary study design

Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Laparoscopic sleeve gastrectomy

Interventions
Patients undergo a laparoscopic sleeve gastrectomy either using a single incision or a conventional multiport technique depending on the surgical team they are assigned to. This is a routine procedure.
There is a one-year follow-up which is not additional to usual treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
A written questionnaire with 0-10 scales is completed at 3 months evaluating:
1. Scar esthetic impact on patients
2. Postoperative parietal pain
3. Impact of the scar on postoperative sex life
4. Scar impact on diurnal quality of life (daily basis movements, work)
5. Scar impact on nocturnal quality of life (sleep)

Secondary outcome measures
1. 6 and 12 months written questionnaires with 0-10 scales evaluating:
1.1. Scar esthetic impact on patients
1.2. Postoperative parietal pain
1.3. Impact of the scar on postoperative sex life
1.4. Scar impact on diurnal quality of life (daily basis movements, work)
1.5. Scar impact on nocturnal quality of life (sleep)
2. 90 days postoperative Morbi-mortality from patient records
3. Bodyweight (kg) (at baseline, 3, 6 and 12 months)
4. Body Mass index (kg/m²) (at baseline, 3, 6 and 12 months)
5. Co-morbidities (at baseline and 12 months) from patient records
6. Incisional hernia rate (at 12 months) with clinical and radiological (CT scan) evaluation

Overall study start date
01/01/2021

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Consecutive patients undergoing laparoscopic sleeve gastrectomy
2. Decision for intervention after multidisciplinary discussion
3. Sleeve gastrectomy as a primary bariatric procedure
4. Body mass index >40 kg/m² or >35 kg/m² with severe comorbidities.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
176

Key exclusion criteria
1. Previous upper abdominal surgery (except laparoscopic cholecystectomy)
2. Patient under guardianship and trusteeship

Date of first enrolment
01/06/2021

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
France

Study participating centre
Hôpital Antoine Béclère
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.aphp.fr/contenu/hopital-antoine-beclere-1

ROR
https://ror.org/04sb8a726

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other