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Can mesh placement prevent port site hernia after sleeve gastrectomy?

Submission date
26/11/2019

Recruitment status
No longer recruiting

Registration date
02/01/2020

Overall study status
Completed

Last Edited
13/07/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Obesity has become the new pandemic, and since the introduction of surgical treatment, bariatric procedures have become one of the most popular types of surgery, with 60,000 procedures performed in France in 2016. Efforts are being made to reduce surgical morbidities, and among them trocar-site hernias. Indeed, data from non-bariatric population define obesity as a major risk factor for developing trocar site hernias. A recent systematic review reported a 24.5% rate of trocar-site hernias after laparoscopic bariatric surgery. In order to prevent reduce the incidence of trocar-site hernia after single-port laparoscopic sleeve gastrectomy, surgeons have been placing prophylactic mesh at the time of the abdominal closure. Reinforcement with either permanent or absorbable synthetic mesh has been performed but the type of material that should be preferred has not been determined. Because of concern regarding long-term mesh complications from prophylactic permanent synthetic mesh, there is interest in absorbable mesh, but there is no convincing evidence that the latter are effective for hernia prevention. The aim of this study is to assess the outcomes of the routine placement of prophylactic permanent or absorbable mesh in preventing the development of trocar-site hernia without increased risk of incisional site complications.

Who can participate?
Adult patients with body mass index > 45 kg/m² undergoing laparoscopic single-port sleeve gastrectomy as a primary bariatric procedure

What does the study involve?
As participants undergoing sleeve gastrectomy (regardless of mesh placement) 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?
Placement of prophylactic mesh is routine care. Possible benefits related to the use of permanent mesh is a reduction of incisional hernia rate with the risk of increased wound infection rate. Compared with permanent mesh, the use of absorbable mesh is possibly less effective in the reduction of incisional hernia rate without increasing the risk of wound infection.

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?
December 2019 to December 2021

Who is funding the study?
Assistance Publique-Hôpitaux de Paris (France)

Who is the main contact?
Dr Hadrien Tranchart
hadrien.tranchart@aphp.fr

Contact information

Type(s)
Public

Contact name
Dr Martin Gaillard

Contact details
Department of minimally invasive digestive surgery
Hôpital Antoine Béclère
157 rue de la porte de trivaux
Clamart
France
92140
+33 (0)1 45 37 43 47
martin.gaillard@aphp.fr

Type(s)
Scientific

Contact name
Dr Hadrien Tranchart

Contact details
Department of minimally invasive digestive surgery
Hôpital Antoine Béclère
157 rue de la porte de trivaux
Clamart
France
92140
+33 (0)1 45 37 43 47
hadrien.tranchart@aphp.fr

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PISM cohort study

Study information

Scientific Title
Prevention of incisional hernia using prophylactic permanent or absorbable mesh following single-port laparoscopic sleeve gastrectomy: a cohort study

Acronym
PRISM

Study objectives
Absorbable mesh is effective for hernia prevention following single-port laparoscopic sleeve gastrectomy

Ethics approval required
Old ethics approval format

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

Study design
Single-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Trocar-site hernia in obese patients undergoing bariatric surgery

Interventions
All consecutive adults patients with body mass index > 45 kg/m² undergoing laparoscopic single-port sleeve gastrectomy as a primary bariatric procedure will be included during a one-year period with a one-year follow-up.

Placement of a prophylactic synthetic mesh is performed routinely at the time of the abdominal closure after single-port laparoscopic sleeve gastrectomy, either with permanent or absorbable synthetic mesh, at the surgeon's discretion.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Occurrence of trocar-site hernia during the first postoperative year observed:
1.1. On CT scan investigating suspicion of trocar-site hernia at the time of systematic routine clinical examination at 1 month, 3 months, 6 months and 1 year after the surgical procedure
1.2. On routine systematic CT scan performed at 1 year of the surgical procedure

Secondary outcome measures
1. Occurrence of complications related to the prophylactic mesh during the first postoperative year:
1.1. Incisional site infection at the time of systematic routine clinical examination at 1 month, 3 months, 6 months and 1 year after the surgical procedure
1.2. Abdominal pain requiring grade III analgesics at the time of systematic routine clinical examination at 1 month, 3 months, 6 months and 1 year after the surgical procedure

Overall study start date
01/12/2019

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Consecutive patients undergoing single-port laparoscopic with prophylactic mesh placement
2. Decision for intervention after multidisciplinary discussion
3. Sleeve gastrectomy as a primary bariatric procedure
4. Body mass index > 45 kg/m²

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
255

Key exclusion criteria
1. Previous upper abdominal surgery (cholecystectomy excepted)
2. Patient under guardianship and trusteeship
3. Patient with known allergy to mesh components

Date of first enrolment
01/01/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
France

Study participating centre
Hôpital Antoine Béclère
Department of minimally invasive digestive surgery
157 rue de la porte de trivaux
Clamart
France
92140

Sponsor information

Organisation
Hôpital Antoine-Béclère

Sponsor details
Department of minimally invasive digestive surgery
157 rue de la porte de trivaux
Clamart
France
92140
+33 (0)1 45 37 43 47
hadrien.tranchart@aphp.fr

Sponsor type

Hospital/treatment centre

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

ROR
https://ror.org/04sb8a726

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Assistance Publique - Hôpitaux de Paris

Alternative Name(s)
Assistance Publique Hôpitaux de Paris, Assistance Publique–Hôpitaux de Paris, AP-HP

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
France

Results and Publications

Publication and dissemination plan
Protocol is not published or available online and no publication of this document is planned. Data analysis will take place in the first months of 2021 and publication will be submitted near the end of 2021.

Intention to publish date
01/10/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/02/2022	13/07/2022	Yes	No