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The weight loss and anti-diabetes outcomes of Sleeve Gastrectomy with Transit Bipartition (SG-TB) and Standard Sleeve Gastrectomy (SG) surgery

Submission date
08/07/2020

Recruitment status
No longer recruiting

Registration date
24/07/2020

Overall study status
Ongoing

Last Edited
21/07/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Weight loss surgery, also called bariatric or metabolic surgery, is sometimes used as a treatment for people who are very obese. It can lead to significant weight loss and help improve many obesity-related conditions, such as type 2 diabetes or high blood pressure.

Sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) are the most popular bariatric procedures currently used. With that being said, SG and RYGB both have limitations of their own. gastroesophageal reflux disease (GERD), diabetes relapse, and weight regain are the issues that may be faced following SG. While RYGB might be able to solve the issues of GERD and diabetes relapse related to SG's, these procedures have an equal weight loss effect. Furthermore, the RYGB procedure creates a risk in that gastric cancer screening is no longer possible. This is worrying especially in countries with high gastric cancer prevalence.

Sleeve gastrectomy with transit bipartition (SG-TB) was introduced in 2012 with the notion that this procedure might be able to solve SG's issues. Currently studies on SG-TB are lacking, especially on the randomized controlled study comparing SG-TB and standard SG procedure. Therefore, this study is aimed to provide an answer for whether SG-TB provides additional benefits against the standard SG.

Who can participate?
Patients aged 18 - 65 years with a BMI of 27 kg/m² or above.

What does the study involve?
Participants will either undergo SG-TB or standard SG surgical procedure over the study period. Participants data on their weight and diabetes conditions as well as prevalence of GERD symptoms and incidence of surgical complications preoperatively and postoperatively will be collected at the start of the study and every 6 months for the 5 years following.

What are the possible benefits and risks of participating?
SG-TB patients might receive longer and superior weight loss and anti-diabetic outcomes than the SG patients. Also fewer SG-TB patients might have GERD symptoms than SG patients.

As SG-TB procedure is a relatively new procedure, there are complications that can occur that have never been previously reported, such as marginal ulcer and severe malnutrition. It has been reported previously that SG-TB might have complications such as incisional or internal hernia and mild malnutrition. On the other hand, standard SG might have increased in leakage and postoperative GERD risks due to the high pressured “sleeve”.

Where is the study run from?
Affiliated Hospital of Xuzhou Medical University (China)

When is the study starting and how long is it expected to run for?
August 2019 to December 2026

Who is funding the study?
Affiliated Hospital of Xuzhou Medical University (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
XYFY2020-JS003-01

Study information

Scientific Title
Weight loss and diabetes remission outcomes on SG-TB versus SG: a randomized controlled trial

Study objectives
1. Transit bipartition is superior or equal to sleeve gastrectomy in inducing weight loss.
2. Transit bipartition is superior to sleeve gastrectomy in inducing diabetes remission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2020, Ethical Committee of The Affiliated Hospital of Xuzhou Medical University (Department of General Surgery, the Affiliated Hospital of Xuzhou Medical University, Huaihai West Road No. 99, Xuzhou Jiangsu 221002, P. R. China; no telephone number provided; zhuxccf@163.com), ref: XYFY2020-JS003-01

Study design
Single-centered interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obesity with or without type-2 diabetes mellitus

Interventions
The study implements a randomized controlled trial (RCT) design (1:1 ratio) involving at least 100 patients undergoing bariatric surgery in total with ≥50 in the sleeve gastrectomy with transit bipartition (SG-TB) group and ≥50 in the standard sleeve gastrectomy group. The study

surgery, data collection, analysis, and evaluation that applies to all groups will be performed by the same individuals. And detailed intervention in intervention arms varies from patient to patient due to the personalized approach. The analysis and reporting of the trial will be in accordance with the CONSORT guidelines.

The overall goal of this particular study is to find out the benefits of SG-TB procedure against the standard SG. In overall:
1. Is SG-TB superior to standard SG in terms of the short-term (1 year) and long-term (>5 years) weight loss outcome?
2. Is SG-TB superior to standard SG in terms of the short-term (1 year) and long-term (>5 years) diabetes remission outcome?
3. The prevalence of gastroesophageal reflux disease (GERD) following both procedures.
4. The early and late complications of SG-TB.

To compare the weight loss efficacy between SG-TB and standard SG, variables that are included are as such: weight (kg), height (m), BMI (calculated using patient's weight and height). In terms of the anti-diabetic outcomes: fasting blood glucose (mmol/L), glycosylated hemoglobin (% HbA1C), fasting insulin and C-peptide; Complete remission is defined as HbA1C <6% without anti-diabetic medications and partial remission as 6-6.49%. These variables will be monitored every 6 months since surgery (at 0, 6, 12, 18, 24, 30, 36, 42, 48, 54, 60 months). In terms of GERD, preoperatively patients will undergo endoscopy for diagnosis as well as history taking of using PPI to solve GERD symptoms; postoperatively all patients will be monitor on the use of PPI as well as performing endoscopy every 1 year since surgery. Early complications are defined as complications that occur within 30 days after the surgery, and late complications as complications occurring in the period following 30 days after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
At surgery, 1-year and 5-year follow-up
1. Weight (kg)
2. BMI (weight, kg divided by the square of height, m)
3. Percentage of Excess BMI Loss, %EBMIL ([(preoperative BMI – postoperative BMI) / (Preoperative BMI – 25)] x 100%")

Secondary outcome measures
1. Diabetes Remission measured at surgery, 1-year and 5-year follow-up using:
1.1. Fasting blood glucose, HbA1C (blood test)
1.2. Anti-diabetic drug usage (patient records)

Overall study start date
01/08/2019

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Age 18-65 years old
2. BMI ≥27.5 kg/m²

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned a total of 100 patients (Each 50)

Key exclusion criteria
1. Type-2 diabetes mellitus of longer than 15 years
2. Previous bariatric surgery
3. Patients debilitated with neurological, cardiovascular and/or malignancies before the procedure
4. Patients refusal to sign the consent form

Date of first enrolment
01/01/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
China

Study participating centre
The Affiliated Hospital of Xuzhou Medical University
No.99 Huaihai West Road
Department of General Surgery
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Sponsor information

Organisation
Affiliated Hospital of Xuzhou Medical College

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Sponsor type
Hospital/treatment centre

Website
http://www.jsxyfy.com/

ROR
https://ror.org/011xhcs96

Funder(s)

Funder type
University/education

Funder Name
Xuzhou Medical University

Alternative Name(s)
, , Xúzhōu Yīkē Dàxué, XZMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
We plan to publish 2 papers, 1-year and 5-year outcomes of the study. The 1-year outcome is expected to be published in early 2022. The 5-year outcome is expected to be published in early 2027.

Intention to publish date
31/01/2022

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