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Bridging of upper part of small bowel with stomach tubing for facilitating weight loss of morbidly obese patients

Submission date
24/05/2020

Recruitment status
No longer recruiting

Registration date
29/05/2020

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Surgery

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

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. But it's a major operation and in most cases should only be considered after trying to lose weight through a healthy diet and exercise.
This study aims to test the safety of a new procedure that combines elements of existing procedures.

Who can participate?
Patients aged over 18 and below 65 years with BMI over 40 kg/m² (without comorbidity related to morbid obesity) or 35 kg/m² (with comorbidity related to morbid obesity, especially glucose metabolism)

What does the study involve?
Patient assessment, performing surgery, and follow up at 1, 3, 6 and 12 months postoperatively.

What are the possible benefits and risks of participating?
Favourable weight loss management is expected due to reducing stomach volume and duodeno-jejunal exclusion but operations may have some risks (gastric wall prolapse, leakage, stricture, bleeding, bile reflux, vomiting, diarrhea, hair loss, nutrient deficiency, hypoproteinaemia and anaemia due to malabsorption)

Where is the study run from?
Kanizsai Dorottya Hospital (Hungary)

When is the study starting and how long is it expected to run for?
October 2018 to October 2020

Who is funding the study?
Kanizsai Dorottya Hospital (Hungary)

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
KDK-2071-2/2019

Study information

Scientific Title
LAparoscopic Single-Anastomosis duodeno-ileal bypass with Gastric plication (SADI-GP) in the maNagEment of morbid obesity (LASAGNE)

Acronym
LASAGNE

Study objectives

Laparoscopic single-anastomosis duodeno-ileal bypass with gastric plication is expected to be a safe procedure and have low complication rates and favourable weight loss outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/07/2019, Kanizsai Dorottya Hospital (Hospital of Nagykanizsa) Institutional Review Board (8800, Nagykanizsa, Szekeres, J.u. 2-8, Hungary; +36 93502092; titkarsag@nkkorhaz), ref: KDK-2071-2/2019

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Laparoscopic surgery for severe obesity and related metabolic disorders

Interventions
Patients were operated on to perform laparoscopic single anastomosis duodeno-ileal bypass with gastric plication. Follow-ups were at 1, 3 and 6 months and are planned at 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Postoperative complications (gastric wall prolapse, leakage, stricture, bleeding, bile reflux, vomiting, diarrhea, hair loss, nutrient deficiency, hypoproteinaemia and anaemia due to malabsorption, venous thromboembolism, pulmonary and cardiovascular events, 30-day hospital readmission) were classified by Clavien-Dindo

Secondary outcome measures
At follow up visits (1,3,6 and 12 months), patients were assessed again by physical examination, blood tests (blood count, ionogram, serum protein, glucose, HgbA1C, iron binding capacity, lipid

profile, kidney and liver function, hemostasis) and BAROS-Moorehead-Ardelt II and Weiner et al. questionnaires. Weight, BMI adjusted to age-gender-ethnics, ideal weight (at BMI: 25), excess of weight, excess of BMI, weight loss, EWL% and TWL% were measured as weight loss outcomes

Overall study start date
16/10/2018

Completion date
29/10/2020

Eligibility

Key inclusion criteria
1. Age over 18 and below 65 years
2. BMI over 40 kg/m² (without comorbidity related to morbid obesity) or 35 kg/m² (with comorbidity related to morbid obesity, especially glucose metabolism)
3. Patient agreement for follow-ups
4. Obtained informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
35

Total final enrolment
36

Key exclusion criteria
1. Bariatric surgery in previous history
2. Severe mental disorders (drug addiction, alcohol consumption, the use of antipsychotics)
3. Socially vulnerable patients
4. Complete immobilization
5. Patients who did not understand the purpose of the study and bariatric surgery

Date of first enrolment
16/10/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Hungary

Study participating centre
Kanizsai Dorottya Hospital
Szekeres Jozsef street 2-8.
Nagykanizsa
Hungary
8800

Sponsor information

Organisation
Kanizsai Dorottya Hospital

Sponsor details
Szekeres Jozsef street 2-8
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Sponsor type
Hospital/treatment centre

Website
https://www.nkkorhaz.hu/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kanizsai Dorottya Hospital

Results and Publications

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

Intention to publish date
30/10/2020

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		27/05/2020	08/06/2020	No	No
Results article		17/08/2021	04/03/2022	Yes	No