

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

<b>Submission date</b> 24/05/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/03/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> 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/m<sup>2</sup> (without comorbidity related to morbid obesity) or 35 kg/m<sup>2</sup> (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?  
Dr Istvan Bence Balint, balint.istvan.bence@kmmk.hu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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/m<sup>2</sup> (without comorbidity related to morbid obesity) or 35 kg/m<sup>2</sup> (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

Nagykanizsa

Hungary

8800

+36 93502000

titkarsag@nkkorhaz.hu

## 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?
<a href="#">Protocol file</a>		27/05/2020	08/06/2020	No	No
<a href="#">Results article</a>		17/08/2021	04/03/2022	Yes	No