

Duodenal switch versus gastric bypass in patients with a body mass index (BMI) greater than 48 kg/m²

Submission date

15/10/2010

Recruitment status

No longer recruiting

Registration date

24/11/2010

Overall study status

Completed

Last Edited

17/08/2023

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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75185

Additional identifiers

Protocol serial number

Ups 03-456

Study information

Scientific Title

Duodenal switch versus gastric bypass in patients with a body mass index (BMI) greater than 48 kg/m²: a prospective randomised controlled trial

Acronym

DS vs RYGBP

Study objectives

Super-obese patients (body mass index [BMI] greater than 50 kg/m²) have lower success-rate in terms of weight loss than obese (BMI 40 - 50 kg/m²). Previous studies have shown greater weight loss after duodenal switch. We want to study weight loss, safety, and post-operative symptoms after these two operations in a randomised trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Ethical Review Board at the University of Uppsala approved on the 19th October 2003

Primary study design

Interventional

Study design

Prospective randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obesity

Interventions

Biliopancreatic diversion with duodenal switch (DS) versus Roux-en-Y Gastric bypass (RYGBP). The aim is to compare perioperative safety as well as long term effects on weight, comorbidities and gastrointestinal symptoms. Follow up is made at three years after surgery, and long term follow up at ten years is planned.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Weight result, measured at 3 years
2. Peri-operative safety, collected at the time of surgery

Key secondary outcome(s)

1. Gastrointestinal symptoms, measured at 3 years
2. Long-term surgical complications, measured at 3 years
3. Metabolical evaluation, measured at 3 years
4. Overall satisfaction, measured at 3 years

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Patients (aged over 18 years, either sex) with BMI greater than 48 kg/m² referred for bariatric surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

47

Key exclusion criteria

1. Language difficulties
2. Previous problems of diarrhoea
3. Suspected inflammatory bowel disease

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Surgical Sciences

Uppsala

Sweden

75185

Sponsor information

Organisation

Uppsala University (Sweden)

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

University/education

Funder Name

Uppsala Universitet

Alternative Name(s)

uppsalauni, Uppsala Universitet, Sweden, Uppsala University, UU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No
Results article	Long-term follow-up	16/08/2023	17/08/2023	Yes	No