ISRCTN10940791 https://doi.org/10.1186/ISRCTN10940791

Duodenal switch versus gastric bypass in patients with a body mass index (BMI) greater than 48 kg/m^2

Submission date	Recruitment status
15/10/2010	No longer recruiting
Registration date	**Overall study status**
24/11/2010	Completed
Last Edited	**Condition category**
17/08/2023	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jakob Hedberg

Contact details
Department of Surgical Sciences
Uppsala University
Uppsala
Sweden
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/m^2: a prospective randomised controlled trial

Acronym
DS vs RYGBP

Study objectives
Super-obese patients (body mass index [BMI] greater than 50 kg/m^2) have lower success-rate in terms of weight loss than obese (BMI 40 - 50 kg/m^2). 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

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
Biliopancreatic diversion with duodenal switch (DS) versus Roux-en-Y Gastic 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/m^2 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)
Uppsala University, UU_University, Uppsala Universitet, Sweden, 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 Participant information sheet	16/08/2023	17/08/2023	Yes	No

Participant information sheet	11/11/2025	11/11/2025	No	Yes