

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

☐ Prospectively registered

☐ Protocol

Registration date
24/11/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
17/08/2023

Condition category
Nutritional, Metabolic, Endocrine

☐ 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Prospective randomised 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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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)

Sponsor details

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Uppsala

Sweden

75185

Sponsor type

University/education

Website

<http://www.uu.se/en/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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