

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

<b>Submission date</b> 15/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/08/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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<sup>2</sup>: a prospective randomised controlled trial

## **Acronym**

DS vs RYGBP

## **Study objectives**

Super-obese patients (body mass index [BMI] greater than 50 kg/m<sup>2</sup>) have lower success-rate in terms of weight loss than obese (BMI 40 - 50 kg/m<sup>2</sup>). 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 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/m<sup>2</sup> 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?
<a href="#">Results article</a>	results	01/05/2012		Yes	No
<a href="#">Results article</a>	Long-term follow-up	16/08/2023	17/08/2023	Yes	No