

Effect of gastric bypass surgery on body weight

Submission date 16/01/2015	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/02/2015	Overall study status Completed	☐ Protocol
Last Edited 15/12/2017	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Background and study aims

Overweight and obesity are increasing and the use of surgery for the treatment of obesity is also rapidly increasing worldwide. This study aims to look at the effects of both diet-induced and surgically-induced weight loss.

Who can participate?

Adults diagnosed with obesity (BMI over 40 kg/m² or BMI over 35kg/m² plus obesity-related problems such as diabetes) and scheduled for surgery.

What does the study involve?

Patients will undergo Roux-en-Y gastric bypass. A number of tests and measurements will be done before and after surgery.

What are the possible benefits and risks of participating?

The benefits are a reduction in body weight (mostly fat tissue); resolution of type 2 diabetes, a disorder in which an organ called the pancreas does not produce enough insulin or the individual's cells do not react to the insulin, leading to high blood sugar levels; and improvements in insulin sensitivity. Risks were not provided at the time of registration.

Where is the study run from?

Xlab, Center for Healthy Aging (Denmark)

When is the study starting and how long is it expected to run for?

December 2009 to December 2016

Who is funding the study?

Innovation Fund Denmark

Who is the main contact?

Professor Flemming Dela

Contact information

Type(s)

Scientific

Contact name

Prof Flemming Dela

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Additional identifiers

Study information

Scientific Title

Effect of gastric bypass surgery on mitochondrial function and insulin secretion and action in patients with type 2 diabetes

Acronym

GASMITO

Study objectives

Weight loss induced with diet and surgery will:

1. Improve insulin action and secretion
2. Increase mass-specific adipose tissue mitochondrial respiration
3. Not change skeletal muscle mass-specific mitochondrial respiration
4. Not reduce maximal fat oxidation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Copenhagen, Denmark (Protocol: H-C-2009-050)

Primary study design

Observational

Study design

Observational study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Insulin resistance

Interventions

Obese patients with and without type 2 diabetes will be assessed twice before and twice after Roux-en-Y gastric bypass with:

1. Intravenous glucose tolerance test
2. Oral glucose tolerance test
3. Euglycaemic clamp
4. Indirect calorimetry
5. Maximal oxygen consumption
6. Maximal fat oxidation rate
7. Dual energy X-ray absorptiometry scan
8. Biopsy samples of skeletal muscle and subcutaneous, hepatic and visceral fat

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Insulin action
2. Insulin secretion
3. Maximal oxygen consumption
4. Mitochondrial respiration
5. Fat oxidation during exercise

Key secondary outcome(s)

1. Body composition
2. Hepatic glucose production and mitochondrial function
3. Lipolysis
4. Incretin hormones

Completion date

31/12/2016

Eligibility

Key inclusion criteria

Before 31/01/2011

1. Age 18–60 years old
2. Body mass index (BMI) $>40 \text{ kg/m}^2$ or $>35 \text{ kg/m}^2$ with obesity-related comorbidities (e.g., type 2 diabetes)

After 31/01/2011

1. Age 25–60 years old
2. BMI $>50 \text{ kg/m}^2$ or BMI $>35 \text{ kg/m}^2$ with obesity-related comorbidities

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Endocrine diseases
2. Dysregulated hypertension
3. Hypertension requiring polypharmacy

Date of first enrolment

01/12/2009

Date of final enrolment

01/07/2014

Locations

Countries of recruitment

Denmark

Study participating centre

Xlab, Center for Healthy Aging

Department of Biomedical Sciences

University of Copenhagen

Blegdamsvej 3

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Denmark

2200

Sponsor information

Organisation

University of Copenhagen

ROR

<https://ror.org/035b05819>

Funder(s)

Funder type

Research organisation

Funder Name

Innovation Fund Denmark

Funder Name

Nordea Foundation

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	01/03/2015		Yes	No
Results article	results	15/07/2015		Yes	No
Results article	results	01/10/2015		Yes	No
Results article	results	01/06/2016		Yes	No
Results article	results	01/07/2016		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	01/12/2016		Yes	No
Results article	results	01/11/2017		Yes	No