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Effect of gastric bypass surgery on body weight

Submission date
16/01/2015

Recruitment status
No longer recruiting

Registration date
17/02/2015

Overall study status
Completed

Last Edited
15/12/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)

Study design
Observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/12/2009

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 kg/m2 or >35kg/m2 with obesity-related comorbidities (e.g., type 2 diabetes)

After 31/01/2011
1. Age 25–60 years old
2. BMI >50 kg/m2 or BMI >35kg/m2 with obesity-related comorbidities

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

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
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/035b05819

Funder(s)

Funder type
Research organisation

Funder Name
Innovation Fund Denmark

Funder Name
Nordea Foundation

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date
31/12/2017

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