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Characterization of the incretin response and microbiota following bariatric surgery, and its role for weight loss – a search for polytherapeutic strategies to combat obesity and ultimately rival surgery

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
03/04/2017

Overall study status
Completed

Last Edited
06/03/2019

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity represents a global epidemic, and increases the risk of developing Type 2 Diabetes Mellitus (T2DM), hence the introduction of the term “diabesity”. The most effective and long-lasting solution for severe obesity is bariatric surgery. Two widely used types of bariatric surgery are gastric bypass and gastric sleeve. Gastric bypass involves re-routing the digestive system past most of the stomach, so less food is digested and it takes much less to feel full. Gastric sleeve involves removing some of the stomach to reduce the amount of food that's required to feel full. Obesity causes changes in the bacteria that live in the gut (microbiota). After bariatric surgery there are changes in the gut microbiota and in intestinal hormones (e.g. GLP-1) that control satiety (fullness) and food intake. Although gut microbiota changes have been suggested to alter levels of GLP-1, the mechanism and its importance in bariatric surgery remain to be determined. The aim of this study is to investigate the changes in the gut microbiota after two different types of bariatric surgery, as well as the relationship with blood levels of GLP-1.

Who can participate?
Women aged 18-65 who are severely obese and not diabetic

What does the study involve?
Participants are randomly allocated into two groups to undergo either gastric bypass or gastric sleeve surgery. Participants are followed for 6 months after surgery, and fecal and blood samples are collected before surgery as well as 3 and 6 months after surgery. Meal-stimulated blood GLP-1 levels are measured before and 3 and 6 months after surgery.

What are the possible benefits and risks of participating?
This study may increase knowledge of the mechanisms controlling obesity and help develop better and less invasive treatments, as well as providing more information regarding the

participant's own outcome of surgery and a more extensive follow-up after surgery. The risks of participating can be considered low as participation only involves repeated blood sampling.

Where is the study run from?
Södertälje Sjukhus AB (Sweden)

When is the study starting and how long is it expected to run for?
February 2017 to September 2020

Who is funding the study?
1. Mats Kleberg Foundation (Sweden)
2. Fredrik och Ingrid Thurings Stiftelse (Sweden)
3. Tore Nilsons Stiftelse för Medicinsk Forskning (Sweden)

Who is the main contact?
Dr Camilla Krizhanovskii

Contact information

Type(s)
Scientific

Contact name
Dr Camilla Krizhanovskii

ORCID ID
https://orcid.org/0000-0003-2195-165X

Contact details
Lagmansvägen 15
Södertälje
Sweden
15286

Additional identifiers

Protocol serial number
nr1

Study information

Scientific Title
Characterization of the incretin response and microbiota in women before an after bariatric surgery, aiming to determine how the microbiota regulates metabolism, and its role for weight loss: a randomized controlled trial

Study objectives
Alteration of gut microbiota following bariatric surgery contributes to its efficacy as a weight loss treatment through modulation of the secretion of the anorectic hormone GLP-1.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala etikprövningsnämnden i Stockholm (regional ethics board in Stockholm), 26/08/2015, ref: 2015/795-31/2

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Non-diabetic patients with severe obesity (that is, BMI >40 kg/m. or BMI >35 kg/m. with comorbidities) will be randomized into two groups receiving either gastric bypass (RYGB) or gastric sleeve. Patients will be followed for 6 months post-surgery, and fecal and blood samples will be collected before surgery, as well as 3 and 6 months after surgery. Meal stimulated GLP-1 plasma levels will be determined prior to and 3 and 6 months after surgery. The primary endpoint is the proportion of subjects achieving a 15% relative change in meal stimulated GLP-1 plasma levels following gastric bypass surgery (RYGB)/gastric sleeve compared to pre-surgical meal stimulated GLP-1 release, as assessed by GLP-1 specific ELISA of serum samples. Secondary endpoints are whether a 15% weight reduction of presurgical body weight is observed following gastric bypass surgery (RYGB)/sleeve.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Plasma GLP-1, measured using the meal tolerance test and GLP-1 specific ELISA of serum samples
2. Gut microbiota composition, analyzed from fecal samples
Timepoints: before 10-day diet, after 10-day diet/before surgery, 3 months after surgery, 6 months after surgery

Key secondary outcome(s))
1. Plasma inflammatory markers, analyzed by specific ELISAs
2. Lipid profile, determined by commercially available HDL and LDL/VLDL Cholesterol Assay Kits, Free Fatty Acid Quantification Kit, as well as Triglyceride Quantification Kit

Timepoints: before 10-day diet, after 10-day diet/before surgery, 3 months after surgery, 6 months after surgery

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Obese non-diabetic females
2. 18-65 years of age
3. Signed informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
Female

Key exclusion criteria
1. Type 2 diabetes
2. Any history of receiving GLP-1 analogues or DPP-4 inhibitors
3. Previous treatment with insulin (any regimen) within 3 months
4. Current or history of drug and alcohol abuse

Date of first enrolment
27/02/2017

Date of final enrolment
30/03/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Södertälje Sjukhus AB
Sweden
15286

Sponsor information

Organisation
Södertälje Sjukhus

ROR
https://ror.org/0376t7t08

Funder(s)

Funder type
Charity

Funder Name
Mats Kleberg Foundation

Funder Name
Fredrik och Ingrid Thurings Stiftelse

Alternative Name(s)
Fredrik and Ingrid Thurings Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Tore Nilsons Stiftelse för Medicinsk Forskning

Alternative Name(s)
Tore Nilsson Foundation, Tore Nilsson Fond

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Camilla Krizhanovskii

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes