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Gut microbiota changes and type 2 diabetes resolution in mild obesity after metabolic surgery

Submission date
21/04/2014

Recruitment status
No longer recruiting

Registration date
01/05/2014

Overall study status
Completed

Last Edited
24/05/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The gut microbiota (microbe population in the intestine) plays a key role in energy storage and development of obesity and type 2 diabetes (T2DM). There are no drugs to cure T2DM successfully. A type of surgery called bariatric surgery has become an alternative, with double benefits: weight loss and glycemic improvement. The aim of the study is to evaluate and compare gut microbiota changes after advanced medical therapy and after surgery and to study associations between gut microbiota changes and metabolic/hormonal changes, including T2DM remission.

Who can participate?
Either male or female patients aged 20-65 years, with a body mass index (BMI) between 30-35Kg /m2. Participants must have been diagnosed with T2DM for at least 3 months.

What does the study involve?
Patients will be randomly allocated to one of two groups: undergo surgery or receive advanced medical therapy. Participants will be evaluated through a 12 months follow-up period, with clinical visits and laboratory tests at months 0, 1, 3, 6 and 12.

What are the possible benefits and risks of participating?
Benefits include loss of weight, glycemic improvement or T2DM resolution. Risks are those related with bariatric surgery.

Where is the study run from?
Centro Hospitalar São João, Porto, Portugal

When is the study starting and how long is it expected to run for?
The study will start on May 2014 and will continue for a period of 16 months.

Who is funding the study?
Liga dos Amigos do Serviço de Endocrinologia, Centro Hospitalar São João, Porto, Portugal

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Proj. 116/13

Study information

Scientific Title
Gut microbiota changes and type 2 diabetes mellitus resolution in mild obesity after metabolic surgery versus advanced medical therapy

Acronym
DM2

Study objectives
In mild obese patients (BMI 30-35 Kg/m2) with type 2 diabetes, metabolic improvement after metabolic surgery is associated with gut microbiota changes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St John's Hospital Ethics Committee, Porto (Centro Hospitalar S. João); ref. 116/13

Study design

Randomized clinical 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
Type 2 diabetes

Interventions
Patients will be assigned to receive either Roux-en-Y gastric bypass (RYGB) surgery with advanced medical treatment as needed or exclusive advanced medical treatment for T2DM
1. Anti-diabetic medical therapy, including lifestyle and nutrition counseling and drug therapy, to optimize weight loss and euglycemic control
2. RYGB surgery

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Assess gut microbiota changes in mild obese (BMI 30-35 Kg/m2) diabetic patients after metabolic surgery and compare the gut microbiota with mild obese (BMI 30-35 Kg/m2) diabetic patients who underwent only advanced medical therapy

Secondary outcome measures
1. Determine the rate of biochemical remission of diabetes after metabolic surgery
2. Assess changes in metabolic, hormonal and inflammatory parameters after metabolic surgery versus advanced medical therapy
3. Study influence of patient characteristics in gut microbiota changes, as well as in metabolic, hormonal and inflammatory parameters, after metabolic surgery versus advanced medical therapy
4. Study associations between type 2 diabetes remission/improvement (metabolic, hormonal and inflammatory changes) and gut microbiota composition/adaptation after metabolic surgery versus advanced medical therapy

Overall study start date

01/05/2014

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Age between 20-65 years old
2. BMI between 30-35Kg/m2
3. Previous diagnosis of type 2 diabetes, according to the American Diabetes Association (ADA) definition, under medical therapy
4. Duration of diabetes more than 3 months
5. Overnight-fasting C-peptide more than 0.7 ng/ml
6. Negative anti-GAD autoantibody
7. Candidate for general anesthesia
8. The ability and willingness to participate in the study, including understanding the requirements of each arm of the study (written informed consent)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A sample size of 20 participants was estimated and 10 participants were randomized by each group.

Total final enrolment
20

Key exclusion criteria
1. Specific contraindication to obesity surgery
2. Diabetes secondary to a specific disease (maturity-onset diabetes of the young, latent autoimmune diabetes in adult and pancreatitis)
3. Received any antibiotic, probiotic, or prebiotic agents in the month before randomization
4. Pregnancy
5. Debilitating disease
6. Psychological conditions which may hamper patients cooperation
7. Any condition which, in the judgement of the investigator, may make the participation in the study risky or bias the results

Date of first enrolment
01/05/2014

Date of final enrolment

31/08/2015

Locations

Countries of recruitment
Portugal

Study participating centre
Rua D. João III, nº 16 1ºH 3030-329 Coimbra
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Sponsor information

Organisation
St. John's Hospital (Portugal)

Sponsor details
Alameda Prof. Hernâni Monteiro
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04qsnc772

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St John's Hospital, Porto (Portugal) (Associação dos Amigos do Serviço de Endocrinologia do Hospital de S. João)

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		21/05/2021	24/05/2021	Yes	No