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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?
Dr Eva Lau
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Eva Lau

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# Additional identifiers

### Protocol serial number
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

### Primary study design
Interventional

### Study design
Randomized clinical trial

### Study type(s)

Treatment

### 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(s)
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

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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**
Coimbra
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3030-329

## Sponsor information

**Organisation**
St. John's Hospital (Portugal)

**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

**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 |