

Duodenal exclusion for the treatment of type 2 diabetes mellitus

Submission date
11/04/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/05/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
07/02/2019

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00456352

Protocol serial number
AS07004

Study information

Scientific Title
Duodenal exclusion for the treatment of type 2 diabetes mellitus

Study objectives

Treatment success based on patients glycaemic control measured by achieving HbA1c level less than 7% as per the American Diabetes Association (ADA) recommendation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics committee (Comite de Etica e Pesquisa do Hospital Sao Camilo) of the Ethics and Research National Committee of the Brazilian Government on the 14th March 2007.

Primary study design

Interventional

Study design

Prospective, single arm, single centre, open label, non-randomised, uncontrolled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type Two Diabetes Mellitus (T2DM)

Interventions

All patients will have the duodenal bypass surgery. The surgery should last anywhere from 40 minutes to one hour. The follow-up visits are scheduled for 2 weeks, 4 weeks, 3, 6, 9, and 12 months post surgery. We anticipate the study duration to be 18 to 24 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Treatment success, evaluated at 6 and 12 months, based on patients glycaemic control measured by achieving HbA1c level less than 7% as per the ADA recommendation.

Key secondary outcome(s)

1. Improvement in physiological measurements (glycaemic control, lipids) (success determined at 6 and 12 months)
2. Co-morbidity improvement, determined by comparing pre-operative co-morbidities to the status post-operatively (success determined at 12 months)
3. Improvement in Quality of Life using the 36-item Short Form (SF-36) questionnaire, determined by comparing pre-operative to post-operative quality of life (success determined at 12 months). We have licensed the SF-36 questionnaire from Quality Metrics and will utilise their guide for interpreting the data

Completion date

11/10/2008

Eligibility

Key inclusion criteria

1. Age between 20 and 65 years old
2. Body Mass Index (BMI) between 23 and 34
3. Oral agents or insulin to control Type Two Diabetes Mellitus (T2DM)
4. Inadequate control of diabetes as defined as HbA1c greater than 7.5 mg/dl
5. Understanding of the mechanisms of action of the treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. More than ten years of T2DM diagnosis
2. More than seven years of insulin use
3. Previous abdominal operations
4. Coagulopathy
5. Liver cirrhosis
6. Unable to comply with study requirements, follow-up schedule or give valid informed consent
7. Currently pregnant (pregnancy test required for confirmation for those of child bearing years)

Date of first enrolment

11/04/2007

Date of final enrolment

11/10/2008

Locations

Countries of recruitment

Brazil

Study participating centre

Av. Pompeia 1178

Sao Paulo

Brazil

SP CEP 05022-001

Sponsor information

Organisation

US Surgical (USA)

ROR

<https://ror.org/00grd1h17>

Funder(s)

Funder type

Industry

Funder Name

US Surgical (USA)

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	01/07/2012	07/02/2019	Yes	No