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Duodenal exclusion for the treatment of type 2 diabetes mellitus

Submission date 11/04/2007	**Recruitment status** No longer recruiting
Registration date 22/05/2007	**Overall study status** Completed
Last Edited 07/02/2019	**Condition category** Nutritional, Metabolic, Endocrine

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00456352

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
11/04/2007

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

Age group
Adult

Sex
Both

Target number of participants
50 patients

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 Paolo
Brazil
SP CEP 05022-001

Sponsor information

Organisation
US Surgical (USA)

Sponsor details
195 McDermott Avenue
North Haven
United States of America
06473

Sponsor type
Industry

Website
http://www.ussurgical.com

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
US Surgical (USA)

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