ISRCTN30845205 https://doi.org/10.1186/ISRCTN30845205

EndoBarrier® Gastrointestinal Liner Diabetes Trial

Submission date
26/09/2014

Recruitment status
No longer recruiting

Registration date
26/09/2014

Overall study status
Completed

Last Edited
15/10/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The management of type 2 diabetes is challenging. Life-long medical therapy and changes in lifestyle (diet and exercise) are poorly accepted by most patients. Therefore, new options for diabetes treatment are required. Patients with type 2 diabetes who undergo obesity surgery (e. g. gastric bypass) see improvements in their blood sugar levels within days (and before they lose weight). However, obesity surgery is rarely used as a treatment for type 2 diabetes because of its expense and risks. This study is designed to see whether a new device called the EndoBarrier, a 60 cm long impermeable sleeve-like device inserted into the intestine, helps patients manage their blood sugar levels, lose weight and reduce other conditions related to obesity compared to standard medical therapy. The EndoBarrier device does not require surgery, yet the device appears to provide similar benefits to patients in terms of improving their blood glucose control. The EndoBarrier device also appears to help people to lose weight and is therefore useful in the treatment of obesity and other health problems related to being overweight e.g. high blood pressure. The purpose of this study is to see how effective the EndoBarrier is compared to standard medical care for diabetes treatment and weight loss and also to better understand the ways in which the EndoBarrier specifically works.

Who can participate?
Patients aged 18-65 who have had type 2 diabetes for at least 1 year.

What does the study involve?
If you are interested in this study we will invite you for a screening visit. If you decide to participate you will be asked to sign an informed consent form. Your doctor will then perform some tests and procedures to determine whether you are eligible for the study. If you are eligible for the study you will be randomly allocated to either receive the EndoBarrier device for 12 months and subsequently a diet for a further 12 months, or you will receive standard medical therapy and a diet for 24 months. All patients will receive specialist support from a doctor specialising in the treatment of diabetes and a dietitian. On some of the study visits, we will also ask you to participate in specific tests which will help us to assess your metabolism, brain activity, insulin sensitivity and food preference. Participation in these tests is entirely optional. More information about these tests can be found in the patient information sheet.

What are the possible benefits and risks of participating?
The direct benefit of taking part in this study will be a possible improvement in your blood glucose and HbA1c, blood pressure, weight loss and reduction in long-term health risks, particularly cardiovascular diseases. The risks associated with the EndoBarrier procedure include the same risks observed with other upper gastrointestinal endoscopic procedures. The EndoBarrier device has been safely used in several clinical trials and in more than 300 subjects with both obesity and type 2 diabetes.

Where is the study run from?
Study visits will either be performed at Imperial College London (St. Mary's Hospital or Hammersmith Hospital in London) or University Hospital Southampton (Southampton General Hospital).

When is the study starting and how long is it expected to run for?
The study will run from November 2014 to November 2018.

Who is funding the study?
NIHR Efficacy and Mechanisms Evaluation (UK).

Who is the main contact?
Natalia Klimowska-Nassar
n.klimowska@imperial.ac.uk

Study website
http://www1.imperial.ac.uk/biosurgerysurgicaltechnology/clinical_trials_outcomes/bariatricsurgery/endobarrier/

Contact information

Type(s)
Public

Contact name
Mrs Natalia Klimowska-Nassar

ORCID ID
http://orcid.org/0000-0003-3655-7436

Contact details
Imperial Clinical Trials Unit
Stadium House
68 Wood Lane
London
United Kingdom
W12 7RH
+44 (0)7764 146 156
n.klimowska@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02459561

Secondary identifying numbers
17212

Study information

Scientific Title
A randomised controlled trial of a duodenal sleeve bypass device (EndoBarrier) compared with standard medical therapy for the management of obese subjects with type 2 diabetes

Study objectives
The management of obesity is challenging and obesity surgery is by far the most effective treatment currently available. Recent medical research indicates that it also improves the management of blood glucose levels in people with type 2 diabetes. Obesity surgery carries different risks and benefits and it is important to balance these by choosing the right procedure for each patient. Therefore new effective strategies to prevent and reduce obesity and its complications such as type 2 diabetes mellitus are needed. This study is designed to see whether a new device called the EndoBarrier Gastrointestinal Liner helps patients manage their blood sugar levels and lose weight. It is a randomised, placebo-controlled trial which compares the potential of the EndoBarrier device with conventional drug therapy, diet and exercise for obesity related type 2 diabetes, and their effectiveness on metabolic state (HbA1c reduced by 20% and blood pressure below 135/85), weight loss, and quality of life. It will further evaluate whether any other conditions that may be related to obesity could become less severe and collect information about complications to determine the safety of the device. The study will also perform various measurements and tests to understand the underlying mechanism of the device. After an initial screening visit to determine patients eligibility, they will be invited for 14 subsequent visits. Patients will be randomised into either having the EndoBarrier device or standard medical therapy treatment for 12 months followed by another 12 months follow-up period. They will also be routinely seen by specialist dietitian who will provide dietetic support throughout the study.

In summary, we hypothesise that this study reduces weight by decreasing hunger, increasing fullness, changing food preference and reducing food reward in obese people with type 2 diabetes. We further hypothesise that the Endobarrier improves glycaemic control with an HbA1C reduced by 20%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London – Fulham, 07/07/2014, ref: 14/LO/0871

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Diabetes; Subtopic: Type 2; Disease: Device studies, Diabetic Control, Hypoglycemia, Metabolic, Nutrition, Obesity

Interventions
EndoBarrier or Standard Medical Therapy: Subject will be either having the EndoBarrier device or standard medical therapy (medication, diet and exercise) treatment for 12 months followed by another 12 months follow-up period. In an attempt to avoid surgery a new device and concept has been developed called a duodenal-jejunal sleeve bypass. The duodenal-jejunal bypass sleeve device (EndoBarrier GI Dynamics Inc, Lexington MA) consists of a single use endoscopic implant in the small bowel and is 60 cm.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
HbA1c; Timepoint(s): 12 months

Secondary outcome measures
1. Cost-effectiveness of the EndoBarrier device; Timepoint(s): 24 months;
2. HbA1c, Blood pressure, weight loss; Timepoint(s): 12 months
3. Long-term cost-effectiveness of the EndoBarrier device; Timepoint(s): 24 months
4. Mechanism of effect; Timepoint(s): 12 months
5. Safety of the EndoBarrier and frequency of adverse events; Timepoint(s): 24 months

Overall study start date
01/11/2014

Completion date
04/01/2019

Eligibility

Key inclusion criteria
1. Age 18-65 years (male or female)
2. T2DM for at least 1 year (HbA1c 7.5-10.0% = 58-86 mmol/mol)
3. On oral T2DM medications (metformin is allowed, but not required)
4. BMI 30-50 kg/m2 with adequate insulin reserve as indicated with insulin C-peptide levels > 0.5 ng/mL

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160

Total final enrolment
170

Key exclusion criteria
1. Language barrier, mental incapacity, unwillingness or inability to understand and be able to complete questionnaires
2. Non-compliance with eligibility criteria
3. Females of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods
4. Current use of insulin
5. Previous diagnosis with Type 1 DM or a history of ketoacidosis
6. Requirement of NSAIDs (non-steroidal anti-inflammatory drugs) or prescription of anticoagulation therapy during the implant period
7. History of iron deficiency and/or iron deficiency anaemia
8. Symptomatic gallstones or kidney stones at the time of screening
9. History of coagulopathy, upper gastro-intestinal bleeding conditions such as oesophageal or gastric varices, congenital or acquired intestinal telangiectasia
10. Previous GI surgery that could affect the ability to place the device or the function of the implant
11. Presence of active H. pylori using C13 urea breath test (if subjects have active H. pylori at baseline, they can receive appropriate treatment and then subsequently enrol into the study)
12. Family history of a known diagnosis or pre-existing symptoms of systemic lupus erythematosus, scleroderma or other autoimmune connective tissue disorder
13. Severe liver (AST, ALT or gGT >4 times upper limit) or kidney failure (serum creatinine >180mmol/l), estimated Glomerular Filtration Rate (GFR) cut-off is 60
14. Severe depression, unstable emotional or psychological characteristics (indicated by Beck

Depression Inventory II score >28)
15. Poor dentition and inability to adequately chew food
16. Planned holidays up to three months following the EndoBarrier Implant
17. Previous EndoBarrier implantation
18. Metal implant unsuitable for MRI scanning and claustrophobia as contraindications for MRI scans (sub-group 1 - fMRI study only)
19. Vegetarian, vegan, gluten or lactose intolerance as unsuitable for fMRI food picture paradigm (sub-group 1 fMRI only)

Date of first enrolment
01/12/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W2 1LA

Study participating centre
University Hospital Southampton
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
c/o Christine Buicke
Joint Research Compliance Office

Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF
-
c.buicke@imperial.ac.uk

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
NIHR Efficacy and Mechanisms Evaluation; Grant Codes: EME 12/10/04

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
05/05/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/11/2017	25/07/2019	Yes	No
Other publications	report	14/11/2019	26/02/2021	Yes	No
Results article	results	01/11/2020	26/02/2021	Yes	No
Results article		14/06/2021	15/10/2021	Yes	No

HRA research summary	28/06/2023	No	No