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Can restricting the blood supply to part of the stomach lead to weight loss in severely overweight patients?

Submission date
25/08/2021

Recruitment status
No longer recruiting

Registration date
27/09/2021

Overall study status
Completed

Last Edited
27/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Recently some studies in animals have shown that if the blood supply to a specific area of the stomach is reduced (the stomach fundus or the top of the stomach), the stomach reduces the production of a hormone called ghrelin. This hormone is the only hormone known to cause an increase in appetite. One of the ways to reduce the blood supply to the stomach fundus is by a procedure called catheter embolisation. This is very similar to other catheter angiograms such as leg or heart angiograms. It can be done painlessly under local anaesthetic in the x-ray room within the hospital and takes usually less than 1 hour to perform. The participants would need to stay in hospital for 2 hours afterwards for observation. Although this procedure has not been done before for weight loss specifically, it is very often done for other conditions like bleeding stomach ulcers and has been shown to be safe in these situations. Indeed some researchers have found that patients having stomach embolisations for bleeding stomach ulcers lost more weight than patients having embolisations to other organs or other areas of the stomach. The aim of this study is to find out whether this could be an effective and safe technique to help with weight loss.

Who can participate?
Patients aged 18 years or older with a body mass index (BMI) between 35 and 50 kg/m², living within 25 miles of the enrolling institution and able to lie face up

What does the study involve?
Participants are randomly allocated to undergo either embolisation or a "sham" procedure. A sham procedure involves a small needle into the wrist under local anaesthetic, but not proceeding any further. The study also involves dietary and exercise advice under the supervision of a specialist dietician and an obesity medicine physician, and routine investigations of blood pressure, blood tests to look at stomach hormones and blood sugar levels, and a simple test to look at the stomach lining (endoscopy) and also at how the stomach empties. The participants are followed up on a regular basis for 12 months. The researchers hope to show that this procedure is effective at reducing weight and improving obesity-related comorbidities.

What are the possible benefits and risks of participating?
There is a possibility that participants will be able to lose weight due to the intervention. There is also a possibility that because of the procedure or medical care, other conditions related to obesity will become less severe or disappear. No serious risks or side effects have been reported with catheter embolisation. To date, only five gastric erosions have been reported (damage to the stomach lining healing within 30-90 days), and one case (out of 65) of pancreatitis (inflammation of the pancreas). Complications during catheter insertion through the artery in the wrist or groin are rare. The risk of a complication occurring is estimated to be less than 1 in 1,000 during every procedure. Complications include artery blocking and local bruising (haematoma). There is a 1-3% (1-3 in 100) risk of bleeding or infection when inserting a catheter through the artery in the wrist or groin.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
August 2021 to July 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Claire Smith, embio@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
247521

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
19SM4996, CPMS 41656, IRAS 247521

Study information

Scientific Title
Left gastric artery embolisation for weight loss in obese patients with BMI 35-50 kg/m²: the EMBIO trial

Acronym
EMBIO

Study objectives
To evaluate the efficacy of left gastric artery embolisation (LGAE) on weight loss and obesity-related comorbidities at pre-determined times points over a 12-month follow-up period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2019, London - Central Research Ethics Committee (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0) 207 104 8007; NRESCommittee.London-Central@nhs.net), REC ref: 19/LO/0509

Study design
Multi-centre double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
The trial interventionist will randomise the patient to either left gastric artery embolisation (LGAE) or a placebo procedure 1 to 1 using the online OpenClinica database. All participants will follow the hospital’s standard tier 3 clinical lifestyle program for weight loss from the time of the intervention up to 12 months.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
Absolute difference in percent weight loss (in kg) measured using weighing scales between baseline weight and weight at 12 months post-treatment

Key secondary outcome(s))
1. Absolute difference in percent weight loss (in kg) measured using weighing scales between baseline weight and weight at 3 and 6 months
2. Total body loss (TBL) i.e. the absolute change in weight (in kg) measured using weighing scales from baseline to 12 months
3. Proportion of patients in each arm with ≥5% TBL measured using weighing scales at 12 months
4. Gut hormones (e.g. blood test for ghrelin, PYY, GLP-1) measured at baseline, month 3, month 6 and month 12
5. Hunger and satiety scores obtained using Visual Analogue Scales at baseline, month 3, month 6 and month 12
6. Food intake measured using meal test and food diaries at baseline, month 3, month 6 and month 12
7. Delay in gastric emptying measured using paracetamol test using participants plasma sample measured at baseline, month 3, month 6 and month 12
8. Eating behaviour and quality of life measured using questionnaires (SF36-V2, IQWOL lite, HADS, DEBQ, EPIC FFQ) at baseline, month 3, month 6 and month 12
9. Markers of obesity-related complications measured by blood tests for HbA1c, fasting glucose, insulin and blood pressure recording at baseline, month 3, month 6 and month 12
10. Frequency of adverse events based on the clinical judgement of the investigator at month 3, month 6 and month 12
11. Preference of treatment arm recorded by asking the participant to indicate their treatment arm preference meaning that they will need to answer the following question during visits at months 3, 6 and 12: ‘Knowing what has happened now - would you have chosen the same procedure?

Completion date
09/07/2024

Eligibility

Key inclusion criteria
1. Adults aged 18-70 years
2. BMI 35-50 kg/m²
3. Ability to lie supine
4. Appropriate anatomy of the left gastric artery and coeliac plexus on CT angiogram
5. Willing and able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Haematological, hepatic or renal dysfunction
2. Weight >150 kg
3. HbA1c >8.5%
4. Known renal, vascular or aortic disease
5. Malignancy
6. Prior major abdominal surgery, prior gastric or bariatric surgery
7. Prior abdominal radiotherapy
8. Gastrointestinal (GI) bleeding or bleeding diathesis
9. Allergy to iodinated contrast,
10. Known gastric ulceration or active H. pylori infection
11. Positive pregnancy test in females of childbearing age
12. Chronic Non-steroidal anti-inflammatory drug (NSAID) use
13. Current use of insulin or sulphonylurea
14. Current use of anti-tricyclic anti-depressants or steroids

Date of first enrolment
14/03/2022

Date of final enrolment
20/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Mary's Hospital
Imperial College Healthcare NHS Trust
Bariatric Clinic
London
United Kingdom
W2 1NY

Study participating centre
University College Hospital
University College London Hospitals NHS Foundation Trust
Bariatric Clinic
235 Euston Road
London
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NW1 2BU

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/09/2023	29/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes