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How is glucose variability changed among people having metabolic surgery, and how does this affect pregnancy and its outcomes?

Submission date
01/09/2025

Recruitment status
Recruiting

Registration date
16/09/2025

Overall study status
Ongoing

Last Edited
15/09/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Metabolic surgeries are successful treatments for obesity and diabetes. In those with diabetes, they can also reduce blood sugar levels. Sometimes, after these surgeries, people start suffering from blood sugar levels which are too low, i.e. hypos. There is evidence that swings in blood sugar levels can occur after surgery - this is where the sugar level after eating spikes at a high level and then is followed by a low sugar level. This phenomenon is called glucose variability. We wish to find out if the different types of metabolic surgery operations are equally as likely to produce these swings in sugar levels and hypos.
In the UK, around 4000 metabolic surgery operations per year are done in women who could become pregnant. Pregnancy in women who have previously had such surgery is an increasingly common situation. Women after Roux-en-Y Gastric Bypass (RYGB) tend to deliver earlier in pregnancy, have smaller babies and the babies have a higher risk of dying. It is not clear whether these problems occur with the other more common type of surgery, sleeve gastrectomy (SG), and the newer mini gastric bypass (MBG).
The aims of this study are:
Study 1: to find out how glucose variability may affect people differently based on the type of metabolic surgery they had.
Study 2: to find out whether the difference in glucose variability may affect pregnancy and children in the longer-term dependent on their surgery and timing of conception. In Study 2, we are also interested in comparing women who get pregnant after having metabolic surgery with a 'control group' - i.e. women who are pregnant without having had surgery.

Who can participate?
Study 1: Men and women over 18 years of age who are planning to undergo metabolic surgery
Study 2: Women who are pregnant or are planning to become pregnant after having had metabolic surgery. We will be comparing these women with others who are pregnant and have not had surgery.

What does the study involve?
Study 1: Participants will be invited to have a study visit before surgery, and at various time

points after surgery. They will wear a continuous glucose monitor (CGM) device for 10 days and check their finger-prick glucose at the same time. They will have clinical assessment and blood, urine and stool tests at the same time.
Study 2: Participants will have a clinical assessment, blood, urine and stool tests and wear a CGM for 10 days while checking their finger-prick glucose at the same time. These will occur before pregnancy, in each trimester of the pregnancy and 3-6 months after they have delivered. During the 2nd trimester, the participant will undergo the routine oral glucose tolerance test as part of clinical care with extra blood tests being taken. All women will receive the usual antenatal NHS care.

What are the possible benefits and risks of participating?
Participants may not benefit directly from participating in the study. However, the information collected from this study will help us understand glucose variability based on different types of metabolic surgery, as well as how this affects pregnancy and children.
Expected side effects include minor discomfort/bruising from blood tests or insertion of the cannula for blood sampling for the 2nd trimester oral glucose tolerance test. The insertion of the CGM sensor may cause minor discomfort or a little bruising.

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

When is the study starting and how long is it expected to run for?
January 2020 to December 2035

Who is funding the study?
1. Diabetes UK
2. NIHR Biomedical Research Centre

Who is the main contact?
Prof. Tricia Tan, t.tan@imperial.ac.uk.

Contact information

Type(s)
Scientific, Principal investigator

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Integrated Research Application System (IRAS)
285211

Protocol serial number
22/0006449

Study information

Scientific Title
Observational study on glucose variability after metabolic surgery

Acronym
GV-MS

Study objectives
1. To measure glycaemic variability in patients undergoing metabolic surgery on a longitudinal basis.
2. To measure glycaemic variability in women who have had metabolic surgery who are planning to become pregnant, and during pregnancy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/01/2021, South Central - Hampshire A Research Ethics Committee (Temple Quay House 2 The Square Temple Quay, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8019; hampshirea.rec@hra.nhs.uk), ref: 21/SC/0038

Primary study design

Observational

Study design
Prospective longitudinal observational study and retrospective observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Glucose variability after metabolic surgery

Interventions
Study 1: Metabolic Surgery:
Participants will be recruited prior to undergoing surgery for Roux-en-Y Gastric Bypass (RYGB), Sleeve Gastrectomy (SG) or Mini Gastric Bypass (MGB). They will undergo blinded continuous glucose monitoring (CGM) study - this will incorporate wearing the CGM for a 10-day period and at the same time completing a food diary and 7-point capillary glucose monitoring. Anthropometrics (including height and weight) and metabolic profiling will be undertaken (i.e. participants will provide plasma, urine and stool).
Participants will be followed up with these same interventions at 1 month after surgery, 3 months after surgery, 12 months after surgery, 24-36 months after surgery, 60 months and 10 years after surgery.

Study 2: Metabolic Surgery and Pregnancy:
Study 2a: Women who have had metabolic surgery ≥18 months ago and who are pregnant or planning to conceive. These women will be matched to 'Controls' who have not had surgery according to their pre-pregnancy BMI and gestational age.
Study 2b: Women who have had metabolic surgery <18 months ago and who are pregnant or planning to conceive. These women will be matched to 'Controls' who have not had surgery according to their pre-pregnancy BMI and gestational age.
Women will be recruited prior to pregnancy where possible and undergo (1) blinded CGM study, (2) anthropometrics (3) metabolic profiling.
The above will occur in pre-conception, in the 1st, 2nd and 3rd trimesters of pregnancy, and 3-6 months post-partum. The participant will undergo the routine oral glucose tolerance test during the second trimester of the pregnancy as part of clinical care, but extra timepoints will be taken to correlate the glucose trajectory with the CGM data. All women will receive routine antenatal NHS care.

Follow-Up at 2, 5 and 10 Years:
Mothers and neonates will be followed up at 2, 5 and 10-years after delivery in order to collect infant and early childhood outcome and clinical data. This will be collected using a questionnaire.

Retrospective Data Collection:
Approximately 25% of reproductive age women become pregnant after metabolic surgery at the Imperial Weight Centre. This allows an opportunity to retrospectively collect data on children and mothers up 10 years after delivery collecting the same outcome and clinical data as the prospective study above. Retrospective data collection from women that have already delivered their babies within the last 10 years since our study began in 2021 (i.e., we will collect data in women that delivered their children from 2011 onwards). Questionnaire data will be

collected identical to the follow-up data collection at 2, 5 and 10-year follow-up. At the same time we will also ask the mothers about their body weight, any new medical diagnoses, medications and blood test results.

Intervention Type
Other

Primary outcome(s)
Glucose variability (GV) is measured using continuous glucose monitoring (CGM) which provides information on mean glucose, Coefficient of Variation, mean amplitude of glycaemic excursions (MAGE), continuous overlapping net glycaemic action (CONGA) and in time in euglycaemic range of 3.5-7.8 mmol/L.
Study 1: measured at baseline (pre-surgery), 1 month after surgery, 3 months after surgery, 12 months after surgery, 24-36 months after surgery, 60 months and 10 years after surgery.
Study 2: measured at preconception, 1st, 2nd and 3rd trimesters, and postpartum.

Key secondary outcome(s)
Metabolic profiling data including weight, blood, urine and stool samples:
Study 1: measured at baseline (pre-surgery), 1 month after surgery, 3 months after surgery, 12 months after surgery, 24-36 months after surgery, 60 months and 10 years after surgery.
Study 2: measured at preconception, 1st, 2nd and 3rd trimesters, and postpartum.

Completion date
31/12/2035

Eligibility

Key inclusion criteria
Study 1:
1. Male or female
2. Aged 18 years upwards
3. Can be diagnosed with diabetes mellitus, pre-diabetes or normal glucose tolerance on basis of WHO 2006 and 2011 criteria

Study 2:
2A: Participants who have undergone metabolic surgery ≥18 months ago and a control group consisting of non-surgical pregnant participants who are gestational age and pre-conception weight-matched.
2B: Participants who have undergone metabolic surgery <18 months ago and a control group consisting of non-surgical pregnant participants who are gestational age and pre-conception weight-matched.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Health condition that would, in the opinion of the investigators, prevent the subject from participating in the study safely
2. Unable or unwilling to wear CGM sensor equipment
3. Previous sensitivity to components of the CGM sensor equipment (for example, the adhesive used for the sensor)

Date of first enrolment
01/04/2022

Date of final enrolment
01/06/2034

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
Shepherd's Bush
London
United Kingdom
W12 0HS

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
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W2 1BL

Study participating centre

Queen Charlotte's and Chelsea Hospital
Du Cane Road
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
NIHR Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan

Published as a supplement to the results publication. All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication