ISRCTN77245085 https://doi.org/10.1186/ISRCTN77245085

Dietary optimisation as a defence against gestational diabetes

Submission date
05/12/2025

Recruitment status
Recruiting

Registration date
13/03/2026

Overall study status
Ongoing

Last Edited
13/03/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Each year, 20 million pregnant women globally, including about 100,000 women in the UK, develop gestational diabetes (GDM) (high blood sugar that begins during pregnancy). This can carry health risks for the mother and baby during pregnancy and later in life and leads to huge challenges in stretched healthcare services.
In pregnancy, the mother's body must adapt to supply fuel and nutrients to the baby. Placenta hormones cause glucose (sugar) to be available for the baby by reducing how well the mother's insulin works. In most women, this change is balanced by making more insulin to keep blood glucose levels stable. However, some women can't increase how much insulin they make so blood glucose levels increase, causing gestational diabetes.
We don't fully understand why some bodies can make more insulin in pregnancy, while others cannot. There are some genetic causes of this, which cannot be changed. However, there must also be non-genetic causes because only about half of women who have gestational diabetes have it again in their next pregnancy. Understanding non-genetic causes may help to find new ways of preventing or managing gestational diabetes.
Previous work by the study team involved a study that recruited 425 participants who had already been diagnosed with GDM. This two-arm, randomised, controlled trial compared a reduced energy diet to a control diet, provided to the participants in the form of 'diet boxes' during the last 8–10 weeks of their pregnancy.
In this study we hope to find out if changing diet and body composition in early pregnancy can change the body's ability to control glucose levels in pregnancy. We will do this through an experimental study using diets designed to reduce body fat (calorie-restricted diet; 1200 kcal) or change where the body stores fat (carbohydrate-restricted diet; 2000 kcal with 25% carbohydrate) and compare these to a control/standard diet (2000 kcal).

Who can participate?
We will recruit 75 women from diverse backgrounds who are ≤16 weeks' pregnant with high risk of gestational diabetes.

What does the study involve?
At baseline, we will measure the participant's body composition, usual diet, and physical activity. We will then randomise the women into three diet groups: 1) control, 2) reduced-calorie and 3)

reduced-carbohydrate. The diets will be supplied weekly to participants' homes from 12-16 to 24-28 weeks of pregnancy. The participants will return for follow-up data collection at appointments which align with their routine clinical care at 20, 24-28, and 36 weeks of pregnancy and at 3, 12 and 24 months after their baby is born.

What are the possible benefits and risks of participating?
Participants in this study will receive food, free of charge, which is designed to be safe, healthy and provide all the nutrients they, and their growing baby need in pregnancy.
They will be tested for gestational diabetes early in their pregnancy. This means they have the opportunity to be treated earlier and have better outcomes if they do develop it. Additional ultrasound and MRI scans will mean that participants get to see their baby's development more often than they would during routine antenatal care.
In addition to the evidence showing that people who take part in clinical research studies benefit from the extra input from healthcare professionals, if this study is successful, the diets could lead to short- and long-term improvements in health for both mothers and their babies.
The risks of taking part in this study are low. The small volume of extra blood required will not be a risk to mother or baby. The risks of having a small calorie or carbohydrate restriction in otherwise healthy women with pre-pregnancy overweight or obesity are thought to be very minimal. Dietboxes provide all the required nutrients for a healthy pregnancy and meet appropriate guidelines. Wearing a sensor for glucose (sugar) could be inconvenient for some women but most people do not find this troublesome.
Taking part in the study will not mean attending more clinic visits compared to usual pregnancy care although it will slightly increase the length of these clinic visits.

Where is the study run from?
The study is recruiting participants from University Hospitals of Leicester NHS Trust and is run from Leicester Diabetes Centre. It is sponsored by University of Leicester (UK).

When is the study starting and how long is it expected to run for?
May 2026 to December 2030

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Sylvia Brooks (Trial Manager), uhl-tr.dodgediabetes.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Claire Meek

ORCID ID
https://orcid.org/0000-0002-4176-8329

Contact details
Leicester Diabetes Centre
Leicester General Hospital

Leicester
United Kingdom
LE5 4PW
+44 (0)1162584023
cm881@leicester.ac.uk

Type(s)
Public

Contact name
Miss Sylvia Brooks

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 (0)116 258 4023
uhl-tr.dodgediabetes@nhs.net

Type(s)
Scientific

Contact name
Dr Laura Kusinski

ORCID ID
https://orcid.org/0009-0008-3164-1106

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 (0)1162584023
laura.kusinski@leicester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
341490

Central Portfolio Management System (CPMS)
61413

Study information

Scientific Title

Maternal diet, body composition and metabolic adaptation to pregnancy

Acronym
DODGE Diabetes

Study objectives
Can reduced calorie and/or reduced carbohydrate diets, delivered to pregnant individuals, who are at high risk of developing gestational diabetes, for a 12 week period, during 12 - 28 weeks of pregnancy, effect maternal glycaemia at 24 -28 weeks gestation.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Single-site open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Other

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
75 pregnant individuals, at high risk of developing gestational diabetes will be recruited and randomised (25 in each arm) to receive one of three dietary interventions in the form of dietboxes containing breakfast, lunch, evening meal and a snack for each day and for around 10 - 12 weeks.

The interventions are:
1. Control: standard diet (2000 kCal; 40% carbohydrate, 35% fat, 25% protein)
2. Active intervention 1: calorie restricted diet (1200 kCal; 40% carbohydrate, 35% fat, 25% protein)
3. Active intervention 2: carbohydrate-restricted diet (2000 kCal; 25% carbohydrate, 50% fat, 25% protein)

Randomisation will occur at the end of the baseline visit and will be stratified by BMI (<40 kg /m2; ≥40 kg/m2) and ethnicity (White ethnicity; Non-White ethnicity). The statistical software package Stata has been used to create four randomisation lists (excel spreadsheets), reflecting the stratification. This will be held by the study manager / administrator who will receive a randomisation call from the clinical team once valid informed consent and baseline data collection is complete. The allocation will be made on a sequential basis from number 1 upwards. The clinical team will be advised of the unique study ID and randomisation allocation and will pass this information onto the participant. The randomisation list will also be shared with the food ordering web-page designer so that the correct meals can be allocated. A paper copy of the randomisation lists will be stored in the master site file and updated after each randomisation.

This paper copy will be available for use if access to the version stored electronically is not possible.

Intervention Type
Behavioural

Primary outcome(s)
Maternal fasting glycaemia measured by a fasting blood sample taken at the time of the 24 - 28 week oral glucose tolerance test (OGTT)

Key secondary outcome(s))
1. Maternal fasting glycaemia measured by a fasting blood sample taken at the time of the baseline (≤16 weeks of pregnancy) oral glucose tolerance test (OGTT)
2. Maternal post-load glycaemia measured by a post-load blood sample at the time of the oral glucose tolerance test (OGTT)
3. Glycaemia TIR (%), TBR, average glucose, CV and SD from Continuous Glucose Monitor (CGM) Data and HbA1c blood sample at baseline (≤16), 20, 24-28, 36 weeks of pregnancy (3 months postpartum HbA1c only)
4. Identification of insulin and indices of insulin resistance or secretion using blood sample collection taken 24-28 weeks of pregnancy when the participant has their routine OGTT (at fasting, 1-hour, and 2-hour post-load timepoints).
5. Identification of lipids using blood sample at baseline (≤16), 24-28 (taken when the participants has their routine OGTT), and 36 weeks of pregnancy.
6. Maternal body composition changes measured using anthropometry and a 3D body scanning app at baseline (≤16), 20, 24-28, 36 weeks of pregnancy and 3, 12, 24 months postnatally. (3D scanning App; baseline (≤16), 24-28 and 36 weeks of pregnancy only).
7. Quantitation of liver and pancreatic fat in pregnancy using MRI at baseline (≤16) and 24-28 weeks
8. Eating habits measured using the 24-hour recall questionnaire (Intake 24) at baseline (≤16), 24-28 weeks and 36 weeks of pregnancy and 3, 12, 24 months postnatal.
9. Eating habits measured using the Three-Factor Eating Questionnaire (TFEQ) at baseline (≤16) and 24-28 weeks of pregnancy and 3, 12, 24 months postnatal.
10. Dietary compliance using 3-day food diary and ordering information. Food diary to be completed at 20 weeks of pregnancy, food ordering to be documented weekly from the start of food intervention at baseline (≤16) until completed at 24-28 weeks.
11. Quality of life measured using the EQ - 5D - 5L at baseline (≤16), and 36 weeks of pregnancy plus 3, 12 and 24 months postnatally.
12. Physical activity using research-grade accelerometers and/or consumer activity monitors at Baseline (≤16), 20, 24-28, 36 weeks of pregnancy and 3, 12, 24 months postnatal.
13. Birth outcomes and delivery information collected from clinical records post delivery.

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Pregnant people aged ≥18 years
2. BMI >25 kg/m2
3. Confirmed pregnancy (≤16 week’s gestation)
4. ≥1 risk factor for GDM (e.g., obesity, family history of diabetes, previous GDM, previous large

baby weighing >4.5 kg, ethnicity at high risk of diabetes, or polycystic ovary syndrome)
5. Willing and able to consent to participate in the trial, with support from an interpreter if needed
6. Planned antenatal care at the same study centre, throughout their pregnancy (i.e. not planning to move away from the region before delivery)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Women with evidence of multiple pregnancies
2. Termination planned
3. Pre-existing comorbidities such as renal failure, severe liver disease, cardiac failure, and psychiatric conditions requiring inpatient admission
4. Medications at the time of recruitment that may interfere with results (e.g., high-dose steroids, immunosuppressants).
5. Severe anaemia at the time of recruitment
6. Confirmed diagnosis of existing type 1 or type 2 diabetes mellitus
7. Haemoglobin A1c (HbA1c) at time of recruitment, indicative of GDM of >48 mmol/mol
8. Specialised dietary requirement (e.g., vegan or severe nut allergy)

Date of first enrolment
01/05/2026

Date of final enrolment
30/04/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Not defined

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available