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Preventing gestational diabetes in pregnant women with obesity at high risk of gestational diabetes (UPBEAT-TIF)

Submission date
09/07/2026

Recruitment status
No longer recruiting

Registration date
19/08/2026

Overall study status
Completed

Last Edited
19/08/2026

Condition category
Nutritional, Metabolic, Endocrine

[ ] 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
Gestational diabetes mellitus (GDM) is a common pregnancy complication that occurs more frequently in women with obesity. It can affect the health of both mother and baby and increase the risk of developing type 2 diabetes later in life.

Women are usually screened for GDM between 24 and 28 weeks of pregnancy, but changes associated with GDM may occur much earlier. A prediction tool has been developed to identify pregnant women with obesity who are at high risk of developing GDM in early pregnancy.

This study aimed to investigate whether early intervention could improve blood glucose control in pregnant women with obesity who were identified as being at high risk of GDM.

Who can participate?
Pregnant women aged 18 years or over with a body mass index (BMI) of 30 kg/m² or higher, carrying a single baby and between 11 and 14+6 weeks of pregnancy, who were identified as being at high risk of developing gestational diabetes.

What does the study involve?
Participants were screened using a prediction tool to identify those at high risk of GDM.

Women identified as high risk were randomly allocated to one of three groups:
- Lifestyle intervention including dietary and physical activity advice
- Lifestyle intervention plus metformin treatment
- Standard antenatal care

The lifestyle intervention was delivered over 8 weeks and focused on reducing dietary glycaemic load and saturated fat intake, increasing physical activity and reducing sedentary behaviour.

Participants attended assessments at the start of the study and after approximately 8 weeks. These included:

- Continuous glucose monitoring
- Dietary assessments
- Physical activity monitoring using a wrist-worn accelerometer

Researchers also collected information on gestational diabetes diagnosis, maternal health and pregnancy outcomes, and newborn health outcomes.

What are the possible benefits and risks of participating?
Participants may have benefited from additional monitoring and support to improve their blood glucose control during pregnancy. The findings may help improve future strategies for preventing gestational diabetes in women with obesity.

Participants allocated to the metformin group may have experienced side effects associated with the medication. The study also involved wearing a continuous glucose monitor, completing questionnaires and attending study assessments.

Where is the study run from?
St Thomas' Hospital, London, UK.

When is the study starting and how long is it expected to run for?
May 2021 to December 2024.

Who is funding the study?
1. Wellcome Trust, UK.
2. Rosetrees Trust, UK.

Who is the main contact?
Dr Sara White, sara.white@kcl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

EU Clinical Trials Register (EudraCT)
2018-000003-16

Integrated Research Application System (IRAS)
235666

Wellcome Trust grant code
208925/Z/17/Z

Study information

Scientific Title
Prevention of gestational diabetes in obese pregnant women; a proof of principle study targeting early pregnancy intervention to women at risk

Acronym
UPBEAT-TIF

Study objectives
To assess in obese pregnant women at high risk of GDM the efficacy of a) lifestyle advice, b) metformin treatment plus lifestyle advice to improve maternal glycaemic control when compared with c) standard care.
To assess feasibility of risk assessment for GDM using a new prediction tool in obese women, to determine the impact of each intervention on a targeted maternal metabolome, to examine the effect of each intervention on dietary intake and physical activity.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/11/2018, London - West London & GTAC Research Ethics Committee (The Old Chapel Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8098; NRESCommittee.London-WestLondon@nhs.net), ref: 18/LO/1500

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose

Prevention

Study type(s)

Health condition(s) or problem(s) studied
Prevention of gestational diabetes mellitus (GDM) in pregnant women with obesity identified as being at high risk of developing GDM.

Interventions
Participants were randomised 1:1:1 to one of three groups: (1) lifestyle intervention consisting of dietary and physical activity advice delivered over 8 weeks; (2) lifestyle intervention plus metformin, initiated at 500 mg daily and titrated up to a maximum dose of 2000 mg/day; or (3) standard antenatal care. The lifestyle intervention focused on reducing glycaemic load, reducing saturated fat intake, increasing physical activity and reducing sedentary behaviour.

Intervention Type
Mixed

Primary outcome(s)
1. Mean 24-hour glucose concentration measured using continuous glucose monitoring (Dexcom G6 CGM) at baseline (13-15+6 weeks’ gestation) and follow up (22-25 weeks' gestation)

Key secondary outcome(s)
1. Mean daytime glucose (07:00 - 23:00 h, mmol/L), mean nocturnal glucose (23:00 - 07:00 h, mmol/L), time in range: % time within 3.5 - 6.7 mmol/L and 3.5 - 7.8 mmol/L , time above range: % time above 6.7 mmol/L and above 7.8 mmol/L , time below range: % time below 3.5 mmol/L (TBR), glucose variability: standard deviation (SD) and coefficient of variation (CV) measured using continuous glucose monitoring (Dexcom G6 CGM) at baseline (13-15+6 weeks’ gestation) and follow up (22-25 weeks' gestation)

2. GDM diagnosis at 24 - 28 weeks' gestation, according to IADPSG and NICE criteria, measured using the diagnosis of gestational diabetes mellitus using a 75 g oral glucose tolerance test at 24–28 weeks’ gestation

3. Dietary intake measured using a semi-quantitative food frequency questionnaire, including glycaemic index, glycaemic load, saturated fat intake and other dietary variables, at baseline at 13–15+6 weeks’ gestation and follow-up at 22–25 weeks’ gestation

4. Physical activity measured using a wrist-worn accelerometer at baseline at 13–15+6 weeks’ gestation and follow-up at 22–25 weeks’ gestation

5. Maternal outcomes, including gestational diabetes, hypertensive disorders, mode of delivery, pregnancy complications and hospital admission, and neonatal outcomes, including gestational age at birth, birthweight, birthweight centile, neonatal complications and neonatal unit admission, measured using data obtained from medical records at delivery and 4-weeks postpartum

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Women over 18 years of age
2. BMI ≥ 30 kg/m²
3. Singleton pregnancy
4. Gestational age between 11 and 14+6 weeks' gestation
5. Willing and able to give informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Insufficient understanding of the trial
2. Inability to provide informed consent
3. Pre-existing diabetes
4. HbA1c ≥ 6.5%
5. Hypertension requiring treatment before or during pregnancy
6. Thyroid disease
7. Coeliac disease
8. Systemic lupus erythematosus
9. Antiphospholipid syndrome
10. Renal disease
11. Thalassemia
12. Sickle cell disease
13. Current psychosis
14. Current metformin treatment
15. Use of medications affecting insulin sensitivity
16. Use of other oral hypoglycaemic medications
17. Steroid treatment
18. Antipsychotic medication use
19. Previous bariatric surgery
20. Multiple pregnancy
21. Participation in another IMP trial
22. Contraindication to metformin
23. Low risk of gestational diabetes according to screening assessment

Date of first enrolment
20/05/2021

Date of final enrolment
28/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
Department of Women and Children's Health, 10th Floor North Wing, St Thomas' Hospital, Westminster Bridge Road
London
England
SE1 7EH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type

Funder Name

Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Rosetrees Trust

Alternative Name(s)
Rosetrees, Teresa Rosenbaum Golden Charitable Trust

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available