ISRCTN18241480 https://doi.org/10.1186/ISRCTN18241480

Ethnic differences in type 2 diabetes pathophysiology

Submission date
20/02/2026

Recruitment status
Recruiting

Registration date
27/02/2026

Overall study status
Ongoing

Last Edited
10/03/2026

Condition category
Nutritional, Metabolic, Endocrine

[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
The DIVERSE Study investigates how people from different ethnic backgrounds respond to a very low calorie diet designed to manage type 2 diabetes (T2D). Previous research has largely focused on White European participants, with limited data on Black African and Caribbean populations. This study compares changes in blood sugar, body weight, fat in organs such as the liver and pancreas, and insulin function before and after a twelve-week diet. The aim is to understand why some people respond better than others and to support the development of more personalised and equitable diabetes treatments.

Who can participate?
The study recruits adults aged 40–65 years with type 2 diabetes who identify as either Black African or Caribbean, or White European. Participation is voluntary, and individuals may withdraw at any point.

What does the study involve?
Participants take part over approximately fourteen weeks and attend 11 visits, mostly at the Leicester Diabetes Centre, with one MRI scan at Glenfield Hospital. The study includes:
• Health checks, blood tests, and monitoring of blood sugar and activity
• Wearing a continuous glucose monitor and physical activity tracker
• Completing a food diary
• Scans to measure body composition and fat in organs (DEXA and MRI)
• Muscle and fat tissue biopsies to study insulin and metabolism
• A twelve-week very low calorie diet using meal replacement products
• Regular consultations with dietitians to monitor progress and provide support

What are the possible benefits and risks of participating?
The study may help participants better understand their personal response to weight loss and blood sugar changes, although benefits are not guaranteed. The research will also contribute to improving diabetes care for diverse populations. Risks are minimal and include mild discomfort from blood sampling, temporary soreness or bruising from biopsies, and negligible exposure to radiation from DEXA scans. All procedures are conducted by trained medical staff.

Where is the study run from?
Leicester Diabetes Centre, with MRI scans at Glenfield Hospital, Leicester, UK.

When is the study starting and how long is it expected to run for?
Individual participation lasts approximately fourteen weeks, from screening to the final assessment.

Who is funding the study?
Funded by Diabetes UK, with additional support from the Leicester Biomedical Research Centre.
The study is sponsored by the University of Leicester.

Who is the main contact?
Study team email: uhl-tr.diversestudy@nhs.net

Contact information

Type(s)
Public, Principal investigator, Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
65477

Integrated Research Application System (IRAS)
351268

Study information

Scientific Title
Exploring ethnic differences in the pathophysiological response to a low-energy diet in people with type 2 diabetes

Study objectives

The main aim of this study is to find out whether people from different ethnic backgrounds respond differently to a structured weight-loss diet when they have type 2 diabetes. Specifically, we want to understand whether a 12-week low-energy diet improves blood sugar control to the same extent in Black African and Caribbean adults as it does in White European adults with type 2 diabetes.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Interventional non randomised

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes - Type 2

Interventions
Baseline assessments (before the diet starts)
Participants attend two detailed assessment visits.
These include measurements of weight, body composition, blood sugar levels, scans to measure body and organ fat, and tests to assess how the body handles sugar and insulin.
Small samples of muscle and fat tissue are taken under local anaesthetic.
Participants also wear glucose and activity monitors and complete food diaries.

12-week low-energy diet
Participants follow a low-energy meal-replacement diet for 12 weeks.
They attend regular visits (about every 2 weeks) for monitoring, blood tests, body measurements, and dietary support.
Participants are closely monitored for safety and side effects.

End-of-study assessments
After the diet, participants repeat the same tests and scans carried out at the start of the study.
This allows researchers to compare changes before and after weight loss.

After the study
Participants receive support to safely return to normal eating.
Some participants may also choose to allow their health data to be followed up through medical records in the future.
All procedures are carried out by trained healthcare and research staff, and participants can withdraw at any time.

Intervention Type

Behavioural

Primary outcome(s)
1. Glycaemic control (HbA1c) measured using blood test at baseline and visit 3, 4, 5, 6, 7

Key secondary outcome(s))
1. Body weight measured using kg at baseline and visit 1, 2, 3, 4, 5, 6, 7, 8, 9

2. Ectopic fat measured using MRI assessment of visceral, hepatic and pancreatic fat at visit 2, 9

3. Insulin sensitivity measured using hyperinsulinaemic-euglycaemic clamp assessment of glucose disposal rate, rate of disappearance and percentage suppression of endogenous glucose production at visit 1, 8

4. Beta-cell function measured using mixed-meal tolerance test assessment of beta-cell function parameters at visit 2, 9

5. Glycaemic variability measured using Continuous glucose monitor assessment of glucose time in range at baseline and visit 2, 3, 4, 5, 6, 7, 8

6. Muscle and adipose tissue characteristics measured using tissue biopsy assessment at visit 1, 8

7. Body composition measured using DEXA assessment of fat and fat-free mass at visit 2, 4, 6, 9

8. Basal metabolic rate measured using indirect calorimetry assessment at visit 1, 2, 3, 4, 6, 8, 9

9. Lipid profile measured using plasma assessment at baseline and visit 3, 4, 5, 6, 7

10. Subjective appetite measured using appetite questionnaire during mixed-meal tolerance test at baseline and visit 2, 3, 4, 5, 6, 7, 9

11. Habitual dietary intake measured using food diary at prior to and during the intervention

Completion date
01/01/2029

Eligibility

Key inclusion criteria
1. Age 40–65y
2. BMI 27–45kg/m²
3. Diagnosed with T2D within the last 6 years
4. HbA1c value >43mmol/mol,if <48mmol/mol individuals should still be receiving antidiabetic medication (mono or dual therapy)
5. Willing and able to consent to participate in the trial
6. Able to understand written and spoken English

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
40 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Current use of insulin
2. HbA1c ≥87 mmol/mol
3. Weight loss of >3kg within the past 6 months
4. eGFR of <30 mL/min/m²
5. Heart failure
6. Participation in another clinical interventional trial
7. Substance abuse
8. Known cancer
9. Myocardial infarction within previous 6 months
10. Current treatment with anti-obesity drugs
11. Pregnancy (or consideration of)
12. Use of antipsychotic drugs

Date of first enrolment
01/04/2026

Date of final enrolment
01/08/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
Leicester Diabetes Centre
Leicester General Hospital NHS Trust
Gwendolen Road
Leicester
England
LE5 4PW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

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

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other