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Capillary markers to predict type 1 diabetes

Submission date
26/11/2025

Recruitment status
Recruiting

Registration date
10/12/2025

Overall study status
Ongoing

Last Edited
10/12/2025

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
This study wants to find easier ways to monitor children and young people with early-stage type 1 diabetes (T1D) such as using finger prick sampling that can potentially be undertaken at home. The oral glucose tolerance test (OGTT) is used to diagnose diabetes and help tell doctors when a person might need treatment with insulin for T1D. At the moment, this test is usually done in a hospital by healthcare professionals as it needs specific knowledge and equipment. It requires the use of a cannula (a plastic tube inserted into the vein) to take a series of blood samples. This can be upsetting and/or painful for children. After the first blood test, the person drinks a sugary drink. The amount of sugar (glucose) in the drink is worked out by the medical staff based on the patient's weight. After the person has the drink there are more blood samples taken. The whole test usually takes 2-3 hours, which can be inconvenient for parents and children causing them to miss out on school or work. Overall, these factors can cause people to refuse to have an OGTT.
There is another blood test that has recently been shown to help predict which children will need insulin in the future. This test measures the amounts of two proteins in the blood, called proinsulin and C-peptide. These proteins are both part of the body's process which makes insulin, and are usually measured from a blood sample taken from a vein.
This study wants to find easier ways to do these tests to allow them to be done in other settings e.g. at home. There are two parts of the study.
Part A – This looks at making the OGTT test easier. This involves two visits: visit 1 to look at whether we can use a finger prick blood test instead of blood from the vein; Visit 2 to test whether a premade glucose drink can be used rather than glucose weighed out based on someone's weight. For these visits we will be using a new kit, the GTT@Home to measure the glucose levels in a drop of blood. We are investigating if this kit, which is already licensed for use in the UK, is suitable for people with early-stage T1D.
Part B - This looks at making the proinsulin: c-peptide test easier by using a finger prick instead of a blood test from the vein. This will be done at the first study visit.

Who can participate?
Children and young people aged under 18 years with two or more diabetes autoantibodies

What does the study involve? (for participants)
This study involves two visits to the hospital for OGTTs, no more than 3 weeks apart, each visit should take around 3 hours. The first visit of this study will be combined with an OGTT the participant is already having, to reduce the number of extra trips to the hospital.

Parts A and B - Visit 1:
For our study, two blood samples - one each for part A and B (each about half a teaspoon of blood), will be taken at the start of the test via the cannula inserted for the OGTT. At the same time, we will collect a finger-prick blood sample (one drop). This drop will go onto panel A of the GTT@home kit. This kit measures how much glucose there is in each drop of blood. We will also collect a drop of blood using a device called a Mitra. This absorbs blood with a sponge and stores the blood sample inside. This sample will be analysed later to measure proinsulin and C-peptide. If it is difficult to get a second drop of blood we can skip this test. The participant will then be asked to drink a sugary drink which has been measured out by the study team, and is based on weight. This will need to be finished within 10 minutes. 2 hours later we will take two more blood samples (about half a teaspoon each), another finger-prick sample for panel B of the GTT@home kit, and a final finger-prick sample with the Mitra. Once the test has finished we will scan the GTT@home kit to upload the data. The glucose results from the data recorder will be sent instantly to a secure database in the United Kingdom, and will be compared to the lab results from the blood samples from the cannula later.

Part A – Visit 2 :
This will be within 3 weeks of visit 1. There is no cannula needed for this visit. We will ask participants to collect a finger prick blood sample at the beginning and place a drop of blood on panel A of the GTT@home device and start the timer. We will then ask participants to drink a premade sugary drink. This drink has been designed to provide enough glucose to perform the OGTT for a range of weights without needing to measure out a specific amount of glucose for each person. 2 hours later we will ask for another finger prick sample for panel B of the GTT@home kit.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants. However, the results of the study may lead to having tests for diabetes that are better tolerated, and less painful for children, young people and their families, and which can be carried out at home.
The finger-prick blood tests may be unpleasant for some people, but any discomfort will settle quickly. There may be a small amount of soreness or redness on the finger.
Participants may experience some brief and/or minor discomfort when blood is taken or the cannula is inserted, we can offer numbing cream to reduce this. Mild bruising or swelling can occur at the site but this should resolve quickly. Occasionally, some people may become lightheaded when they have their blood taken.

Where is the study run from?
The study is being coordinated from the University of Oxford (UK)

When is the study starting and how long is it expected to run for?
December 2025 to July 2026

Who is funding the study?
UKRI via the Horizon Europe Guarantee Scheme

Who is the main contact?
The study team can be contacted at edent1fi_wp3@ndm.ox.ac.uk

Contact information

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Public

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Additional identifiers

Central Portfolio Management System (CPMS)
64043

UKRI Grant code
10112483

Integrated Research Application System (IRAS)
342301

Study information

Scientific Title
Determining minimally invasive alternatives to glucose, proinsulin and C-peptide in early-stage type 1 diabetes

Study objectives
Part A (OGTT): Primary Objective:
To determine the agreement of capillary blood glucose levels to venous blood glucose levels during a standard OGTT

Part A (OGTT): Secondary:
1. To determine the diagnostic accuracy of capillary blood glucose levels at diagnostic thresholds
2. To determine the diagnostic accuracy of weight-banded, standardised glucose loads in children with early stage T1D

Part B (Proinsulin:C-peptide): Primary Objective:
To determine the agreement of capillary proinsulin and C-peptide levels to venous levels during a standard OGTT

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/07/2025, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8029; southbirmingham.rec@hra.nhs.uk), ref: 25/WM/0089

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
49 children with two or more diabetes autoantibodies and aged <18 years of age, will be invited to take part. They will be identified from research established research monitoring programmes where they are already taking part in venous OGTTs. To ensure we have a spread of glucose values, we will aim to recruit approximately equal numbers of participants in stages 1 and 2 T1D i.e. those with 2 or more IAbs but who have normal glucose levels (stage 1) or slightly abnormal

glucose levels (stage 2). To aid in recruitment stratification, we will use a recent HbA1c or OGTT (within the previous 6 months), where available, to aid categorisation of glycaemia. An effort will also be made to recruit participants across a range of ages.

This study involves two visits to the hospital or research centre for OGTTs no more than 3 weeks apart, each visit should take around 3 hours. Before each visit the participant will need to fast for at least 8 hours (this would be when they are sleeping, and they can still drink water).

Study Visit 1:
1. Baseline information including date of birth, gender and ethnicity will be collected as well as height and weight.
2. A cannula will be inserted to collect blood samples. Two blood samples will be taken from the cannula at the start of the test, to measure glucose, proinsulin and C-peptide. At the same time, a fingerprick blood sample (one drop) will be collected. This drop will go onto panel A of the GTT@home kit which is being provided by Digostics Ltd for the study, and measures glucose. A second one or two drops of blood will be collected using a device called 'the Mitra'. This absorbs blood with a sponge and stores it inside the device. This sample will be analysed later to measure the proteins proinsulin and C-peptide.

If it is difficult to get a second drop of blood we can skip this test.
1. The participant will drink a sugary drink, which has been measured out by the study team based on their weight, within 10 minutes.
2. 2 hours later, two more blood samples will be taken from the cannula (about half a teaspoon each) to measure glucose, proinsulin and C-peptide, and another finger-prick sample for panel B of the GTT@home kit to measure glucose and a final one or two drops of blood for the Mitra will be collected, for later measurement of proinsulin and C-peptide.

Study Visit 2:
This will be within 3 weeks of visit 1. There is no cannula needed for this visit. This starts at least 8 hours after an overnight fast, as per Visit 1.
1. A fingerprick blood sample will be collected on panel A of the GTT@home device and start the timer, to measure glucose.
2. The participant will then drink a premade sugary drink based on a band of weight. This drink has been designed to provide enough glucose to perform the OGTT for a range of weights without needing to measure out a specific amount of glucose for each person.
3. 2 hours later another finger prick sample will be collected for panel B of the GTT@home kit, to measure glucose.

If the participant is having regular OGTTs we may ask if they want to be in our study again. We will also be asking permission to keep any samples that are left over after they have been analysed to be used in future research. Once each visit has finished, the GTT@home kit will be scanned using a mobile phone app which allows the data to be uploaded. By scanning the app, this allows the glucose results from the data recorder to be sent instantly to a secure database in the United Kingdom, and will be compared to the laboratory results from the blood samples from the cannula later. We will snap off the data recorder and store this securely in case we need to check the results again. The blood samples taken from the cannula and in the Mitra device will be frozen at the site and then shipped to the study's central laboratory at the University of Swansea where they will be analysed.

Intervention Type
Other

Primary outcome(s)
1. Agreement between capillary and venous blood glucose measures in readings (mmol/L) measured using Bland and Altman method and in classification of glycaemic stages by Cohen's Kappa at baseline (fasting) and 0 and 120 minutes post glucose load.

Key secondary outcome(s))
Secondary (Part A):
1. Sensitivity and specificity of capillary glucose at 5.6 mmol/L, 7.0 mmol/L (fasting), and 7.8 mmol/L and 11.1 mmol/L (120 min) using classification by venous samples as the reference standard.
2. Agreement between OGTT readings after individualised glucose load and weight-banded, standardised glucose load on the capillary device in two separate visits taking place within clinically acceptable time interval using Bland and Altman method and in classification of glycaemic stages by Cohen's Kappa. Measured using baseline (fasting), 0 and 120 minutes at visit 1 and visit 2.

Primary (Part B):
Agreement between capillary and venous serum proinsulin and C-peptide measures using Bland and Altman plot method and intraclass correlation. Measured at baseline (fasting) and 0 and 120 minutes post glucose load.

Completion date
01/07/2026

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation, or assent with parental consent
2. Aged <18 years old
3. Able to consume oral glucose drink within 10 minutes
4. Presence of diabetes autoimmunity (>=2 islet antibodies)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 years

Upper age limit
17 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. On insulin treatment for diabetes
2. On any medication that may interfere with glucose metabolism (including but not limited to steroids)

Date of first enrolment
01/12/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Czech Republic

Germany

Portugal

Study participating centre
University of Oxford
University Offices
Oxford
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OX1 2JD

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

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
Data sharing statement to be made available at a later date