

Non-invasive glucose monitoring study

Submission date 01/04/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/07/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

More and more people are living with diabetes, which is putting a significant strain on the NHS and other healthcare systems globally. Current continuous glucose monitoring devices (CGMs) have greatly improved treatment, especially for young patients with Type 1 diabetes. However, these CGMs involve inserting a sensor beneath the skin using a needle, which can be painful and cause skin damage and irritation. This study aims to test a new device called 'Glucopatch' to see if it can measure glucose levels as well as current CGMs. The 'Glucopatch' is unique because it sits on the skin surface and does not require needle insertion, making it painless to use.

Who can participate?

We are looking to recruit about 30 children and young people (CYP), aged 5-18 years, from our diabetes clinics at Bristol Royal Hospital for Children (BRHC).

What does the study involve?

Participants will wear the 'Glucopatch' for 2 weeks each. They or their family will need to do four blood tests (finger pricks) a day and record these in a diary and research mobile phone. They will wear a new 'Glucopatch' every day, and glucose measures from these will be sent to a special research mobile phone. Participants and families will not know what these readings say, as we have not yet proven that the device is accurate for people living with diabetes. All diabetes care will continue using the participant's usual CGM.

At the end of the 2 weeks, participants and/or their families will return to BRHC to give back the research mobile phone, any remaining devices, and diaries. They will report any issues they had with 'Glucopatch' and arrange an interview with a researcher to discuss their overall thoughts on 'Glucopatch' and suggest improvements. We will also ask for consent to compare the usual care CGM glucose results with the 'Glucopatch' glucose levels.

What are the possible benefits and risks of participating?

There are no direct benefits to taking part in this study. However, if the new technology is successful in measuring glucose levels accurately, it could lead to further work to get NHS adoption eventually. Risks include the inconvenience of daily finger pricks and potential issues with the 'Glucopatch' device.

Where is the study run from?

The study is run from Bristol Royal Hospital for Children (UK)

When is the study starting and how long is it expected to run for?

April 2025 to January 2026

Who is funding the study?

The study is funded by the Small Business Research Initiative (Call 23) from Innovate UK.

Who is the main contact?

Professor Julian Hamilton-Shield, j.p.h.shield@bristol.ac.uk

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

354992

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2025-651

Study information

Scientific Title

Non-invasive, and needle-free, continuous glucose monitor for children and young people living with diabetes

Acronym

NORMS

Study objectives

That a non-invasive patch (produced by Transdermal Diagnostics, called 'Glucopatch') applied to the skin of young people living with type 1 diabetes can measure interstitial glucose to a comparable level of accuracy to current invasive continuous glucose measuring devices used in clinical diabetes management.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 01/07/2025, East of England – Cambridge East (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048037; cambridgeeast.rec@hra.nhs.uk), ref: 25/EE/0129

Study design

Single-centre open-label patient-blinded single-arm proof of concept study

Primary study design

Observational

Secondary study design

Proof of concept: glucose results obtained from 'Glucopatch' accurately measure interstitial glucose levels reflecting Gold Standard capillary glucose tests.

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Type 1 diabetes

Interventions

Preliminary Wearability study: up to 5 young people aged 5-<18 years living with diabetes attending the Bristol Royal Hospital for Children Diabetes Service will be asked to wear the 'Glucopatch' device for 4 to 5 hours in the Children's Hospital Research ward to check suitable sites for wearing device, ease of attachment and use, check that data downloads to Transdermal Diagnostics app on dedicated mobile phone which will be stored in a server cloud accessible to TD and research team. Finally this study will generate further information on patient preferences for use.

Main Study: 30 young people aged 5-<18 years living with diabetes will be recruited from the ~550 patients attending the Bristol Royal Hospital for Children Diabetes Service. Once assent /consent has been received, the patient and family will attend a baseline meeting with the research nurse to:

(1) Explain the device usage including application, requirements for downloading data to a mobile app (provided by Transdermal), when to take finger pricks and how to record accurate date and time of measures as well as actual value. Two finger pricks will be requested pre-meals (Breakfast and tea-time) and two about 2 hours after these meals. This meeting will take about an hour.

(2) The family will then take the devices home and apply a new device each evening before bedtime. The family will be asked to take finger pricks each day (x4) and record times and dates for accurate comparison with new device downloaded data.

(3) After 10 days or at a convenient time for the family, they will return the finger prick diary, an adverse event diary (this will be explained to participants and families: skin irritation, device falling off prematurely etc.) and any remaining devices. The family will take part in a short interview with the research associate to establish preliminary perceptions of the device and problems encountered with device usage: the researcher and participants can use the adverse event diary as a prompt. This whole visit will take approximately one hour.

Each patient and their finger prick and usual CGM data will be allocated a unique identifying number to allow comparison with the downloaded data from the new device on interstitial glucose measures. This data set will also record the age of patient, sex and ethnicity (we will purposively recruit to have at least 30% (n~10) of the cohort from Black, East and South Asian young people).

Analysis of device accuracy will be done by consensus error grid analysis (also known as the Parkes error grid) which was developed as a tool for evaluating the accuracy of blood glucose meters in 2000(J L Parkes, et al. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care 1 August 2000; 23 (8): 1143–1148. <https://doi.org/10.2337/diacare.23.8.1143>). The accuracy of a new device aims to measure clinical risk posed by an inaccurate result. At least 99% of all readings should fall in brackets A and B compared to gold standard finger pricks (Zone A represents no effect on clinical action; zone B represents little or no effect on clinical outcome). Furthermore, we will analyse another metric called Mean Absolute Relative Difference (MARD) which is the average difference between a device measurement (or test result) and the reference measurement (finger prick glucose) at normal to high glucose levels. For a successful device, this should be <10%.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Glucopatch-24

Primary outcome measure

Glucose measured:

1. From finger-prick blood glucose x 4 a day for 10-14 days (Units being mmol/l), patient recorded in diary and in dedicated mobile phone app
2. Contemporaneous interstitial glucose measures by Glucopatch (Units mmol/l), recorded by a dedicated mobile phone app
3. Contemporaneous glucose data recorded from currently used CGM (Units mmol/l), downloaded from cloud-based patient records with consent

Secondary outcome measures

Qualitative data by individual interviews, either face to face or by telephone after the 2-week study period wearing the Glucopatch, will explore the following themes:

1. Previous experience and benefits/issues using current and past CGM
2. Family and patient opinion of Glucopatch
3. Potential benefits of non-invasive technology
4. Potential issues with non-invasive technology
5. Ease of application and removal
6. Any discomfort from using patches

Overall study start date

01/04/2025

Completion date

18/01/2026

Eligibility

Key inclusion criteria

Child or Young Person living with type 1 diabetes on CGMS and any form of insulin therapy.

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

Children in diabetes service with any other form of diabetes (Type 2, CFRD, MODY) or not on CGMS for management of diabetes.

Date of first enrolment

31/07/2025

Date of final enrolment

31/12/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

NIHR Bristol Biomedical Research Centre

University Hospitals Bristol NHS Foundation Trust

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Study participating centre

Bristol Royal Hospital for Children

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Sponsor information

Organisation

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Funder(s)

Funder type
Industry

Funder Name
SBRI Healthcare

Results and Publications

Publication and dissemination plan

Technology conferences and peer reviewed papers. A summary written by Transdermal Diagnostics for participants and possibly a paper in a diabetes journal.

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at termination of the clinical study in early 2026.

IPD sharing plan summary

Data sharing statement to be made available at a later date