ISRCTN15382728 https://doi.org/10.1186/ISRCTN15382728

Non-invasive glucose monitoring study

Submission date
01/04/2025

Recruitment status
Recruiting

Registration date
02/04/2025

Overall study status
Ongoing

Last Edited
07/05/2026

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
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 June 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

Contact name
Prof Julian Hamilton-Shield

ORCID ID
https://orcid.org/0000-0003-2601-7575

Contact details
Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ
+44 7703066901
j.p.h.shield@bristol.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
354992

Central Portfolio Management System (CPMS)
68843

Protocol serial number
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

Study type(s)
Diagnostic

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Glucopatch-24

Primary outcome(s)
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

Key secondary outcome(s))
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

Completion date

30/06/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 years

Upper age limit
18 years

Sex
All

Total final enrolment
0

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
01/01/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Bristol Biomedical Research Centre
University Hospitals Bristol NHS Foundation Trust

Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
England
BS28BJ

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
SBRI Healthcare

Results and Publications

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
Other