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Safety and tolerability of a skin sensor for glucose and lactate

Submission date
01/05/2026

Recruitment status
Not yet recruiting

Registration date
19/06/2026

Overall study status
Ongoing

Last Edited
28/07/2026

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Skin sensors, often applied to the back of the arm, are now widely used by patients with diabetes. Sensors with a similar design can also be used to detect other important markers. A new skin sensor has been designed in the University of Liverpool that detects glucose and lactate at the same time. It is hoped that this sensor could be used as a part of a patient monitoring system, designed to give early warning of deterioration and monitor how a patient is responding to treatment.
The purpose of this study is to check that this new skin sensor is safe and comfortable. The study will also provide information about how accurate the sensor is compared to ordinary blood tests.

Who can participate?
Healthy volunteers aged 18-45 years

What does the study involve?
There will be three groups of 5 participants in the study:
In group 1, a ‘blank’ sensor will be applied for 8 hours. This means the needles will not detect glucose and lactate. This allows the safety and comfort of the basic materials to be checked.
In group 2, a standard sensor will be applied for 8 hours that detects glucose and lactate.
In group 3, a standard sensor will be applied for 24 hours that detects glucose and lactate.

In groups 2 and 3, readings from the sensor will be compared to results from blood tests taken whilst the sensor is worn. After removal of the sensor, the skin will be checked and any issues will be recorded.

What are the possible benefits and risks of participating?
This is a healthy volunteer study without anticipated benefit to volunteers. The information provided on the safety, comfort and accuracy of the sensor will help the development of the sensor and monitoring system. This could benefit future patients who become unwell and need close monitoring. Insertion of the sensor may be associated with risks such as pain, bleeding, irritation and infection at the site of insertion.

Where is the study run from?
The NIHR Liverpool Clinical Research Facility, UK.

When is the study starting and how long is it expected to run for?
September 2026 to November 2026.

Who is funding the study?
The UK Medical Research Council.

Who is the main contact?
Dr Greta Wood, greta.wood@liverpool.ac.uk

Contact information

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Scientific, Public

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Integrated Research Application System (IRAS)
368419

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223502/Z/21/Z

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343008/Z/25/Z

Study information

Scientific Title
Safety and tolerability study of a minimally invasive microneedle sensor for monitoring glucose and lactate

Study objectives
The study aims to test the safety and comfort of a skin sensor in healthy volunteers. The sensor detects two biomarkers, glucose and lactate, that can be helpful for patient monitoring.

Primary Objective: To evaluate the safety and tolerability of a biosensing device detecting lactate and glucose.
Secondary Objective: To evaluate the accuracy of the device compared to gold-standard measurements.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design

Observational

Secondary study design
Pre-clinical medical device development

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
This study involves 15 healthy volunteers divided into three groups of five. The research is designed to test a new wearable skin sensor (a biosensor) that uses tiny "microneedles" to measure two health markers, glucose and lactate. The sensor will be tested in three ways: a "blank" sensor with no sensing ability worn for 8 hours to test the basic model (Group 1), a functional sensor worn for 8 hours (Group 2), and a functional sensor worn for 24 hours (Group 3).

Procedure: A small plastic tube (cannula) will be placed in the participant’s arm or hand to allow for easy blood sampling. After 15 minutes, the biosensor will be applied to the same arm and covered with a clear dressing. A matching dressing (without a sensor) will be placed on the other arm for comparison. The upper limb (arm) used for the sensor application will be decided randomly for each individual within a Group.

Group 1: Participants wear a "blank" sensor for 8 hours. They will provide one blood sample at the start and complete a questionnaire about their comfort and any pain.

Group 2: Participants wear a standard sensor for 8 hours. The sensor is connected by a thin wire to a recording device. To check the sensor's accuracy, a small blood sample will be taken through the cannula every hour.

Group 3: This follows the same process as Group 2, but the participant wears the sensor for a full 24 hours. They will go home with the sensor in place and return the following day for its removal and a final blood test.

When the sensor is removed, the study team will take photographs of the skin and check for any redness or irritation.

Visit 2 - Removal (Group 3 only)
Group 3 participants will return for sensor removal and a final blood test the following day.

Follow-up Visit - All
In groups 1 and 2, participants will return for follow-up 24 hours after Visit 1. In group 3, participants will return for follow-up 24 hours after Visit 2.
Any adverse events will be recorded, and a photograph will be taken of the biosensor application site.

Final Remote Check
To ensure there are no delayed skin reactions, all participants will be asked to take a photo of their arm at home 24 hours after their follow-up visit and send it to the research team.

The total duration of observation is up to 24 hours.
The total duration of follow-up is up to 48 hours.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Liverpool microneedle glucose and lactate sensor

Primary outcome(s)
1. Safety measured using absence of serious adverse events and absence of needle breakage at end of follow-up

2. Tolerability measured using Visual Analogue Scale pain score less than 3 out of 10 at point of sensor removal

Key secondary outcome(s)
1. Accuracy measured using a comparison of sensor-derived glucose and lactate measurements with time-matched venous reference measurements obtained using the Siemens RAPIDPoint 500e Blood Gas System at 1 hour and at each interim measurement until device removal

Completion date
22/11/2026

Eligibility

Key inclusion criteria
1. Male or Female, 18-45 years of age
2. Be in good health
3. Able and willing to comply with all study requirements
4. Negative pregnancy test (female participants)

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
The participant may not enter the study if ANY of the following apply:
1. Previously diagnosed chronic medical condition
2. Female participant who is pregnant, lactating or planning pregnancy during the course of the study
3. Predisposition to bleeding
4. Predisposition to skin infection or inflammation including a history of atopic dermatitis
5. Participants who have participated in another research study involving an investigational product in the past 12 weeks or plan to participate during the course of the study
6. Under investigation for malignancy
7. Allergy to any component of sensor

Date of first enrolment
21/09/2026

Date of final enrolment
20/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Liverpool Clinical Research Facility
Royal Liverpool University Hospital
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Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	version 1.2	01/05/2026	26/05/2026	No	No