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POET: Use of point of care testing for monitoring and management of long-term conditions

Submission date
11/04/2024

Recruitment status
Recruiting

Registration date
17/06/2024

Overall study status
Ongoing

Last Edited
13/11/2025

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
Currently there is more focus in increasing the use of technology in healthcare. This can be in ways such as virtual consultations, electronic health recording and the use of remote monitoring tools to manage those with long term conditions like diabetes, or cardiovascular disease. Through the use of technology in healthcare settings, we can improve patient experiences and free-up clinic time.

This is also highlighted during the current COVID-19 pandemic where healthcare services have undergone important transformations including virtual consultations when face-to-face consultants were not always possible. Since the start of the pandemic, 75% of diabetes consultations within University Hospitals of Leicester NHS trust have been taking place virtually.

For people with diabetes, collecting and measuring blood samples including HbA1c measurement remain an important part of routine health care and monitoring. This allows health care providers to make important decisions on diagnosis of diabetes and provides a good way to monitor diabetes control. Sample collection is usually measured during a visit to the hospital or a health care setting. However, the collection of blood samples remains a barrier for successful remote working as this requires face-to-face contact.

In this study we are investigating if the remote Point Of Care Testing (POCT) (which uses blood samples collected via finger prick methods at home) can be used to monitor diabetes control and measure other routine blood samples without having to visit the hospital. This will allow Health Care Providers (HCPs) to make decisions and take action in a timely manner during the virtual consultations.

The overall aim of this study is to see if POCT is accurate compared to normal collection of blood samples using a vein and understanding patient experiences and thoughts around remote blood collection.

Who can participate?
People aged 18 years or older, with long-term conditions (LTC) or healthy individuals attending UHL or primary care centres for routine blood sample or assessments

What does the study involve?
Routine blood tests involve a visit to the hospital or GP surgery for the bloods to be taken from a vein by a trained member of the health care staff. This procedure can be painful and consumes a lot of time travelling and having to wait for the staff to take bloods.

We want to do a study to test if the bloods taken by finger prick method at home are as accurate as the bloods taken from a vein which will save time for the patient, avoid hospital or GP visits and will be less painful.

The study has two parts : In the first phase or validation phase, we will approach patients visiting the hospital or GP surgery for their routine blood tests and check with them to see if they are happy to have a few drops of blood collected via finger prick method at the same time as they are having bloods drawn for their routine checks from a vein. This may mean also collecting some additional bloods that are not part of their routine care for which they were visiting the hospital or GP surgery but need to be collected as part of this study.
After collection, we will then send these samples to the lab for testing to see if these bloods collected via finger prick method are as accurate as taking bloods from a vein. We are looking to recruit 420 participants for this first phase.
If found accurate, we will then move to the second phase of the study also called the feasibility phase. During this second phase, we will invite 100 participants who took part in the first phase of the study. These participants will be sent self-testing packs with instructions to collect a few drops of blood at home and post back to the lab for testing using a return envelope already provided in the pack. This is to find out how convenient it is for people to finger prick and collect samples themselves at home and send back to the lab and to check if the samples collected at home are still accurate compared to blood samples taken through the vein in the first phase of the study.
We will also interview 20 participants who took part in both phases of the study to find out their experience of the whole process of having bloods collected via finger prick method instead of having samples collected from a vein, their confidence in the results and if they would be happy to have routine bloods taken via this method in the future.

What are the possible benefits and risks of participating?
If found successful, we anticipate that this will save time for both patients and the NHS staff, will be less painful compared to bloods taken from the vein, will avoid extra visits to the hospital and GP surgeries and will save money for the NHS. We do not expect any serious harm to the participants except for mild pain from a finger prick.

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
September 2022 to May 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309342

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61804, NIHR201165, IRAS 309342

Study information

Scientific Title
Use of Point Of carE Testing (POET) for monitoring and management of long-term conditions (LTCs): A validation and feasibility study

Acronym
POET

Study objectives
The overall aim of this study is to see if POCT is accurate compared to normal collection of blood samples using a vein and understanding patient experiences and thoughts around remote blood collection.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/05/2024, REC East Midlands – Leicester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048143; leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0071

Study design
Observational qualitative

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Diabetes

Interventions
People need to come to hospital for routine bloods which can often be difficult and painful. In this study we want to see if we can use blood obtained through finger prick method (similar to what people with diabetes do to check their blood glucose) instead of blood obtained from a vein to check routine bloods and this will avoid visit to hospital/GP practice where people can collect blood by finger prick at home and mail it back to the hospital. This is likely going to be less painful and save you time.

The study will be divided into two phases:
- The initial Validation phase - in hospital / primary care
- followed by the Feasibility phase - at home

VALIDATION PHASE:
In the validation phase of the study, eligible adult participants visiting out-patient departments or phlebotomy services at UHL will be identified and consented. There are no special requirements for the blood tests and almost anyone visiting healthcare facilities for routine bloods can take part. A member of the study team will check whether participants are eligible to take part in the study. We will receive consent and address any questions they may have before we take samples. We will also collect brief information about their medical history and details about their age, race and gender. We will then collect blood samples from them (both from a vein and via finger prick method). The blood drops collected via finger prick will be collected in both a small tube and directly onto a piece of filter paper. The entire process will take about 30 minutes or less. We will aim to approach 420 participants during this initial validation phase.

FEASIBILITY PHASE:
In this phase, we will contact 100 participants with long-term conditions like diabetes who took part in validation phase. We will mail them a testing kit with all equipment along with a questionnaire to their home address. They will be requested to collect a few drops of blood in a small tube and again on a piece of filter paper using a finger prick.
They will also be requested to complete a short survey/questionnaire which will take 1-2 minutes about their experience. They will then be requested to mail the samples directly to the hospital lab in a pre-paid envelope provided with the testing kit and mail the survey to Leicester Diabetes Centre in a separate envelope also included with the testing kit.
From the 100 participants who took part in the Feasibility Phase, we will separately contact 20 of those (if consented) to take part in a one-off interview. Interviews will be conducted remotely either Via Phone call or video call (Microsoft Teams) and will be carried out at a time convenient to the participant.
Once we have received the capillary micro-samples, we will analyse them in the UHL pathology

lab and find out if the results obtained are similar to the routine bloods obtained via vein and if we can use it instead of routine bloods which require hospital/surgery visit.

Intervention Type
Other

Primary outcome(s)
Validation of capillary blood samples against venous samples:
1. HbA1c
2. Potassium
3. Sodium
4. Urea
5. Creatinine
6. Total Cholesterol
7. Low Density Lipoprotein (LDL) – Cholesterol
8. High Density Lipoprotein (HDL) – Cholesterol
9. Triglyceride (TG)
10. ALT (Alanine Aminotransferase)
11. CRP
12. TSH (Thyroid Stimulating Hormone)
Validation Phase: Months 1 – 12
Feasibility Phase: Months 13 - 18

Key secondary outcome(s))
Feasibility outcomes measured in months 13 - 18
1. Service User experience: Surveys and interviews
2. Adherence rate: Proportion of responders returning the remote samples.
3. Cost-effectiveness analysis: Compared to standard venous samples

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Aged >18 years of age
2. People with long-term conditions (LTC) (a subset will be consented separately for the feasibility phase) or healthy individuals attending UHL or primary care centres for routine bloods or assessments, e.g. elective surgery
3. Able to understand written and spoken English
4. Able to give informed consent
5. Participant agrees to have capillary and venous blood samples collected.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnant women with gestational diabetes or established diabetes
2. Those on dialysis or end stage renal disease (eGFR< 15ml/min/m2)
3. Liver cirrhosis
4. Diagnosed cancer
5. Haematological malignancies
6. Needle phobia
7. Clotting disorders and bleeding tendencies (platelet count < 100 x 109/L)
8. Conditions in which HbA1c measurement is not reliable
9.1. Hemoglobinopathies like sickle cell and thalassemia
9.2. Severe hypertriglyceridemia (> = 20mmol/l)
9.3. Splenectomy
9.4. Chronic alcohol intake of more than 14 units per week
9.5. Blood transfusion within past 12 weeks
9.6. Recent blood loss (< = 4 weeks)
9.7. Ribavirin and interferon-alpha use
9.8. Iron, B12 and folate deficiency anaemias

Date of first enrolment
06/11/2024

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square

Leicester
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LE1 5WW

Study participating centre
NIHR CRN: East Midlands
Knighton Street Outpatients
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Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
All hard and electronic copies of data collected in this study will be identified by a unique study identification code. The link between the participant and their study ID number will be retained by the host NHS organisation which is University hospitals of Leicester (UHL) NHS Trust Welcome to Leicester's hospitals website (leicestershospitals.nhs.uk) in a secure office environment and with access restricted to members of the research team. All electronic data will be password protected on UHL server and accessible only by delegated members of the

research team during the active phase of the study and until the data have been analysed. Paper copies such as CRFs will be stored in a locked cabinet within the Leicester Diabetes Centre Leicester Diabetes Centre.

The type of data that will be shared:
All research data, whether online or paper-based, will be transcribed onto the research database by a delegated member of the research team and any identifiable participant data will be pseudonymised and managed in accordance with ICH-GCP, UK Policy Framework for Health and Social Care Research and the most up-to-date version of the Data Protection Act 2018 and General Data Protection Regulation (GDPR) before sharing with the third parties or outside of the host organisation.

When the data will become available and for how long:
The data will become available after the recruitment of the last participant and will be available for 12 months after completion of the study.

By what access criteria the data will be shared including with whom, for what types of analyses, and by what mechanism, whether consent from participants was obtained, comments on data anonymisation, any ethical or legal restrictions, any other comments:
The data will be pseudonymised and any patient identifiable data will be removed before sharing with third parties or outside of the host organisation on their request or where the host organisation is unable to analyse the data. The consent for this will be taken from all the participants where data is shared, and this is made explicitly clear in the consent form.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	15/04/2024	05/02/2025	No	Yes