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Gaining patient feedback on the use of finger prick blood tests at home

Submission date	**Recruitment status**	[X] Prospectively registered
07/12/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2024	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Up to 60% of the adult population live with a chronic condition and 40% have more than one. Many, if not most, require blood tests at intervals to track illness progression or to monitor for side effects of prescribed drugs. Alongside this, the wider use of remote clinics during the COVID-19 pandemic has led to a change in strategy whereby many patients now monitor their health status at home through home recording of blood pressure, oxygen saturation, weight, and exercise tolerance. There is also now the potential for this to be supplemented by home monitoring of blood tests. These tests are easy to undertake. Microsampling is similar to diabetic patients who check their own sugar levels. The primary aim of the study is to show that blood tests used in routine monitoring can be undertaken with a high level of accuracy and satisfaction by patients using microsampling test kits.

Who can participate?
Adults who are under the care of a hospital clinic. People may be approached to participate if they are attending an outpatient appointment or if they are on a hospital ward.

What does the study involve?
Participants will have their usual venous bloods taken and alongside this will be asked to take bloods themselves using one of three different microsampling kits. The researchers will determine the accuracy of these kits compared to the venous bloods and compare patient satisfaction with each of the kits using a feedback questionnaire. Clinical care pathways will not be changed.

What are the possible benefits and risks of participating?
There are no clinical benefits to participating. Doing so will involve having to self-administer a sharp needle to the skin of a finger to draw blood. This may cause some temporary discomfort.

Where is the study run from?
Salford Royal Hospital and Wythenshawe Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2022 to December 2023

Who is funding the study?
Salford Clinical Commissioning Group (UK)

Who is the main contact?
Prof. Darren Green, darren.green@nca.nhs.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Darren Green

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310182

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21KID04-S, IRAS 310182

Study information

Scientific Title
Patient experience and accuracy of finger prick blood testing kits

Study objectives
The aim of the study is to show that blood tests used in routine monitoring can be undertaken with a high level of accuracy and user satisfaction by patients using microsampling test kits. The secondary aim is to compare the accuracy of results and user satisfaction between three different types of microsampling devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2022, London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8171; bromley.rec@hra.nhs.uk), ref: 22/LO/0379

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Adult patients under the care of secondary care clinics who are having regular blood tests as part of usual care

Interventions
Patients will be recruited from inpatient wards and outpatient clinics at the two hospital sites. After consent is taken bloods will be collected as follows:

Patients will be allocated to one of the three microsampling kits as per the flowsheet. For “limited bloods” patients will be allocated to either the Mitra or Captainer devices on an alternating basis. All patients requiring extensive blood panel or haematology tests will be allocated to the Microtainer system. The devices will be labelled with the patient study ID.

Patients will be given the microsampling kit and instructions and allowed to familiarise themselves with these. They will then have usual clinical bloods taken with the drawing of up to two extra bottles (max 10 ml). These bottles will be labelled with study ID only. Usual bloods will be sent to the local lab for analysis as per clinical care. The extra bottles will be kept by the study team and sent to the study lab with the microsamples.

After usual bloods are taken, the patients will be asked to take bloods themselves using the microsampling kit. The study team member will then put these with the study venous bloods for delivery to the reference lab. Bloods will not be retained for future research, samples will be destroyed in line with the disposal of clinical samples ins usual practice. In the case of any

spillages, standard infection control procedures should be followed as outlined in the Trust policy.

Patients will be given a feedback questionnaire to complete. This will be anonymous and can either be given to a ward staff member or retained by the patient for completion at a later date and posted back to us.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BD Microtainer microsampling kit

Primary outcome measure
Bias between fingerprick and venous sampling for routine biochemistry assays measured using Bland-Altman analysis at single timepoint

Secondary outcome measures
Comparison of quantitative and semi-quantitative patient feedback between different fingerprick devices measured using a standardised feedback questionnaire at single timepoint

Overall study start date
29/05/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adult patients under the care of secondary care clinics having blood tests taken as an inpatient or outpatient as part of usual care
2. Patients must have the capacity to provide consent and be able to undertake finger prick testing themselves

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Needle phobia
2. Peripheral neuropathy or vascular disease affecting hands
3. Known infection with a blood-borne pathogen (HBV, HCV, HIV)

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Northern Care Alliance NHS Foundation Trust

Sponsor details

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England
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rowen.norton2@nca.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Salford CCG

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal. Local report and business case model / HE analysis to be provided to Northern Care Alliance (NCA), Manchester University Hospitals NHS Foundation Trust (MFT) and Clinical Commissioning Groups (CCGs).

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No