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Project COMFORT Study- Understanding how new blood sampling devices for use at home compare with standard hospital vein blood tests

Submission date 07/05/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/05/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 08/05/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Every day in the UK, hundreds of thousands of blood tests are done to check people's health, diagnose illnesses, and track treatments. Blood tests also form an important part of many medical research studies. These tests usually need a trained healthcare worker in a hospital or clinic to take a blood sample from a vein in the arm using a needle. Although this is quick and reliable, many people find it inconvenient, and it can be difficult or uncomfortable.

New types of blood sampling devices, called patient-centric microsampling (PCmS), are now available. These are simple and safe tools that people can use at home to collect small blood samples. This could make it easier for people to have blood tests done when it would otherwise be difficult or inconvenient, making healthcare and research participation more accessible.

In the Project-COMFORT Study, we want to understand how PCmS compares with standard blood tests taken from a vein. We will look at how good the samples are, how easy the devices are to use, and what the experience is like for patients.

Who can participate?

Adults aged 18 years or older who have cardiovascular disease or who are at higher risk of it can take part. This includes people with conditions such as high blood pressure or high cholesterol. Participants must be able to understand the study and follow the instructions.

What does the study involve? (for participants)

The study has two parts. People can choose to take part in one part or both.

In part A, participants attend one hospital visit. They answer some questions about their health and lifestyle. A healthcare professional takes two blood samples. One is a standard sample from a vein using a needle. The other is a small sample from the upper arm using a microsampling device. Participants then complete a short questionnaire about their experience.

In part B, participants also attend one hospital visit at the start. They are shown how to use the microsampling device at home. They are given three kits to take home. They then collect three small blood samples at home, at least 7 days apart. Each sample is posted to a laboratory using prepaid packaging. After this, participants complete a questionnaire about their experience.

What are the possible benefits and risks of participating?
Participants are unlikely to receive a direct personal benefit. However, the study may help improve how blood samples are collected in the future, making testing easier and more convenient for others.

There are some small risks. Blood sampling may cause discomfort, bruising, or bleeding. Some people may feel dizzy or faint. There is also a small chance that test results could show findings that would not have caused problems but may lead to further tests or worry. The study team will explain any results clearly if needed.

Where is the study run from?
The study is run from Ninewells Hospital in Dundee by the University of Dundee (UK).

When is the study starting and how long is it expected to run for?
July 2026 to July 2027.

Who is funding the study?
The study is funded by the EU Innovative Health Initiative through the Innovate Guarantee scheme.

Who is the main contact?
Professor Isla Mackenzie, memo-info@dundee.ac.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Prof Isla Mackenzie

ORCID ID
https://orcid.org/0000-0002-3680-7127

Contact details
MEMO Research, Ninewells Hospital, University of Dundee
Dundee
United Kingdom
DD1 9SY
+44 1382 383119
memo-info@dundee.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)

368292

Study information

Scientific Title
Project-COMFORT Study: Patient-centric blood sampling for improved healthcare

Acronym
Project-COMFORT Study

Study objectives
Primary objectives:
Part A: To confirm that a PCmS sample collected by clinical staff at the study site can achieve a reliable result comparable to a conventional venepuncture sample
Part B: To evaluate the success rate of PCmS self-collection across participant disease populations

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Approximately half sequential and half single

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Cardiovascular disease (CVD) or elevated cardiovascular risk

Interventions
Potential participants will be identified by a member of their NHS clinic health care team. Potential participants will be asked at their clinic visit if they would be willing to speak to a member of the research team about what is involved in taking part in the study. This can be

either after their clinic visit or if they prefer at another time. At this eligibility visit the study will be explained to the participant, eligibility will be checked and those interested in taking part in the study will sign an informed consent form. At informed consent participants will be able to choose whether they wish to take part in Part A only (hospital blood sampling), Part B only (home sampling using the Tasso+ blood microsampling device) or to take part in both Part A and Part B.

Participants taking part in Part A only will have one study visit. At their study visit baseline data about their general health and wellbeing will be collected and their height and weight will be measured. A health care professional will then take a 7.5-5ml (~ 1 teaspoon) venous blood sample and a 500µlPCmS blood sample (~ a tenth of a teaspoon) taken using a Tasso+ device. At the end of the visit the participant will be asked to complete the Part A usability questionnaire to gather their views on their experience of venous and Patient Centric micro Sampling (PCmS) blood sampling. Participants will be given the choice to complete the questionnaire online or on paper during their study visit.

Participants taking part in Part B will have one study visit. At this study visit baseline data about their general health and wellbeing and their height and weight will be collected. A healthcare professional will show them a Tasso+ device explain how to use it and how to send back their samples from home. The participant will be given 3 devices to take home along with instructions and packaging to return their samples to the NHS laboratory at Ninewells Hospital. Participants in Part B will take 3 PCmS samples at home at least 7 days apart and return each of their samples via Royal Mail using the packaging provided. Once they have completed their 3 at home blood samples participants will be asked to complete the Part B questionnaire to gather their views on their experience of PCmS blood sampling at home, sending the samples back to the laboratory and the training materials they received. Participants will be given the choice to complete their questionnaire on paper (by post in a stamped addressed envelope), by telephone with a member of the study team or online via a survey link.

Participants who choose to take part in Part A and Part B will have one study visit. At this study visit baseline date about their general health and wellbeing and their height and weight will be measured. A healthcare professional will then take 7.5-5ml (~ 1 teaspoon) venous blood sample and a 500µlPCmS blood sample (~ a tenth of a teaspoon) taken using a Tasso+ device. At the end of the visit the participant will be asked to complete the Part A usability questionnaire to gather their views on their experience of venous and PCmS blood sampling either on paper or online. The healthcare professional will then explain how to use the Tasso+ device and how to send back their samples. Participants will be provided with 3 devices to take home along with instructions and packaging to return their samples to the NHS laboratory at Ninewells Hospital. Participants will take 3 PCmS samples at home at least 3 days apart and return their each of their samples via Royal Mail using the packaging provided. Once they have completed their 3 at home blood samples participants will be asked to complete the Part B usability questionnaire to gather their views on the experience of PCmS blood sampling at home, sending the samples back to the laboratory and the training materials they received. Participants will be given the choice to complete their questionnaire on paper (by post in a stamped addressed envelope), by telephone with a member of the study team or online via a survey link.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
TASSO+

Primary outcome(s)
1. Part A: Concentrations of selected analytes in venous and PCmS-collected blood samples measured using Laboratory Analysis at Day 1

2. Part B: 1. Percentage of participants who successfully perform at least one PCmS self-collection according to instructions. 2. Percentage of participants who successfully perform three PCmS self-collections according to instructions. 3. Percentage of self-collected PCmS samples fulfilling expected laboratory quality criteria (e.g., volume, time frame for shipping /receiving, haemolysis/clotting, and suitability for analysis). measured using Laboratory analysis and questionnaires at Day 1, Day 7 and Day 14

Key secondary outcome(s))

Completion date
01/07/2027

Eligibility

Key inclusion criteria
For all participants in Part A and Part B:
1. Age ≥ 18 years at the time of signing informed consent
2. Confirmed diagnosis of cardiovascular disease or elevated cardiovascular risk, including, but not limited to, atherosclerotic cardiovascular disease, hypertension, hyperlipidaemia (Investigator opinion)
3. Able to participate in all planned study visits
4. Able to understand the nature, objectives, and procedures of the study, and to provide written informed consent before any study-related procedures
5. Willingness and capacity to comply with all protocol-required activities, including blood sample collection using venepuncture and PCmS using a Tasso+ device

In addition, for participants in Part B (self-collection or assisted self-collection):
1. Access to a stable home environment suitable for sample collection
2. Able to follow written or visual instructions for the Tasso+ device and associated sampling kit, with assistance from a family member or a caregiver, if required
3. Ability to comply with sample labelling, packing, and returning by post, as specified in participant instructions

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

100 years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Presence of any medical, psychological, or social condition or treatment that, in the opinion of the investigator, may interfere with the participant's ability to comply with any study procedures or may increase the risk associated with study participation
2. Presence of any skin infection or damage at the intended sample collection sites
3. History of hypersensitivity to skin adhesives, e.g., sticking plasters or dressings
4. Enrolment in another clinical study or trial involving interventions that, in the investigator's judgment, could interfere with the endpoints of the Project-COMFORT study

Date of first enrolment
06/07/2026

Date of final enrolment
01/06/2027

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type

Funder Name
Innovative Health Initiative

Alternative Name(s)
The Innovative Health Initiative, Innovative Medicines Initiative, IHI, IMI

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available