ISRCTN13589405 https://doi.org/10.1186/ISRCTN13589405

Blood collection for the development of a point-of-care troponin platform

Submission date 18/04/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 17/05/2024	**Overall study status** Completed	
Last Edited 17/05/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
The measurement of cardiac biomarkers in blood (particularly troponin) to aid in the diagnosis of heart attack (myocardial infarction) is well established. If the concentration of troponin is sufficiently low when first measured, a significant proportion of chest pain patients can be safely discharged, which could be expedited by a point-of-care test.
Psyros Diagnostics are developing a point-of-care blood testing platform that will allow rapid measurement of troponin, based on a novel technology that uses single-molecule-counting. Individual troponin molecules are tagged with a photoactive reagent, then captured on a fluorescent sensor surface. Once bound, activation with light bleaches the fluorescence around each molecule allowing single molecules to be counted.
As part of the product development process, it is critical to have access to fresh whole-blood patient samples to validate that the test works sufficiently well before committing to a full-blown clinical study for regulatory approval. As part of the development process, it is also important to confirm that variations in the haematocrit of the blood (the percentage of red cells in the blood) do not impact the troponin measurement being carried out.

Who can participate?
Adults over 18 years, who have arrived at A&E with chest pains and symptoms of myocardial infarction.

What does the study involve?
In this study, fresh whole blood samples will be collected by venepuncture from chest pain patients known to have elevated troponin levels. These samples will then be measured on a prototype instrument.
In addition, a fraction of the blood taken will have the cellular components removed and the acellular plasma will be stored for future testing. No cellular material will be stored for more than 24 hours.
We aim to collect up to 120 samples over a 6-12 month timeframe. Samples will be collected in batches of approximately 20 and tested on prototype instruments. The data will then be fed into performance optimisation and the system will be re-tested on the next batch of samples.

What are the possible benefits and risks of participating?
The only benefit is the satisfaction of assisting in a study. The main risk is localised bruising at the point where the blood sample is taken.

Where is the study run from?
Psyros Diagnostics (UK)

When is the study starting and how long is it expected to run for?
April 2024 to September 2025

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

Who is the main contact?
Dr Steve Ross, sar@prolightdx.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333438

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 333438, NIHR206488

Study information

Scientific Title
Blood sample collection for final product development and estimation of clinical sensitivity and specificity of a point-of-care troponin test based on single molecule counting

Study objectives
The study will provide fresh blood and samples for testing a prototype point-of-care blood test for troponin. The results will be used to confirm that the system functions properly, give the same result for plasma and whole blood and can compensate for variations in hematocrit.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted (United Kingdom)

Study design
Blood sample collection study to confirm prototype in vitro diagnostic performance

Primary study design
Other

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis of myocardial infarction

Interventions
Blood collection study for testing on prototype point-of-care in vitro diagnostic platform.

Participants are first consented to take additional blood samples. They are given up to 3 hours to review the participant information sheet. If they consent, then up to 20 ml of blood is taken into lithium heparin tubes. This takes approximately 5 minutes. There is no further intervention or follow-up.

Intervention Type
Other

Primary outcome(s)
The concentration of troponin in the blood sample is measured 10 times to estimate the imprecision of the prototype device being tested. Similarly, the concentration of troponin is measured in the corresponding plasma sample 10 times to estimate the imprecision in the measurement. The measured concentration in the blood and plasma samples from all patients are compared to estimate the degree of correlation. Blood samples are taken at a single timepoint.

Key secondary outcome(s))

The measured hematocrit on the prototype device is compared to the measurement on a hematocrit centrifuge to estimate the correlation. Blood samples are taken at a single timepoint.

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Capacity to give consent
2. >18 years of age
3. Presentation at ED with chest pains and symptoms of myocardial infarction
4. Measured troponin concentration > 10 ng/L in previous 24 hours.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Key exclusion criteria
1. Age <18 years
2. Inability to give consent

Date of first enrolment
01/08/2024

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St. Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Psyros Diagnostics

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study are not expected to be made available due to the fact they are used during product development.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes