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

Submission date 18/04/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/05/2024	**Overall study status** Ongoing	
Last Edited 18/08/2026	**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 March 2028

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

Integrated Research Application System (IRAS)
333438

National Institute for Health and Care Research (NIHR)
206488

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)
Approved 28/08/2024, West Midlands - Edgbaston REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; edgbaston.rec@hra.nhs.uk), ref: 24/WM/0149

Primary study design
Other

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

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
01/03/2028

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
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

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

Date of first enrolment
04/06/2025

Date of final enrolment
01/02/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

St. Thomas' Hospital
Westminster Bridge Road
London
England
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

IPD sharing plan summary
Not expected to be made available