

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

<b>Submission date</b> 18/04/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/05/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/05/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

### Contact name

Dr Steve Ross

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

333438

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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)

Not yet submitted (United Kingdom)

## Study design

Blood sample collection study to confirm prototype in vitro diagnostic performance

## Primary study design

Other

## Secondary study design

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

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

## 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 measure

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

18/04/2024

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

90 Years

### **Sex**

Both

### **Target number of participants**

120

### **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**

England

United Kingdom

**Study participating centre**

**St. Thomas' Hospital**

Westminster Bridge Road

London

United Kingdom

SE1 7EH

**Sponsor information****Organisation**

Psyros Diagnostics

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<https://prolightdx.com/en/>

**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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/07/2026

**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