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Specimen collection study for diagnostic test development

Submission date
29/01/2026

Recruitment status
Recruiting

Registration date
08/02/2026

Overall study status
Ongoing

Last Edited
10/03/2026

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Doctors and healthcare professionals use blood tests to help understand why people are unwell and to decide what care they may need. These blood tests are called in vitro diagnostic tests (IVDs) and are performed on a blood sample outside the body, usually in a laboratory, clinic, or sometimes at home.
When new diagnostic blood tests are being developed, researchers need to check how well they work by comparing them with tests that are already in routine clinical use. Traditionally, a separate research study is needed for each new test, which can be time-consuming and costly and may delay new tests becoming available to patients and the NHS.
This study aims to support the development of new blood tests by collecting blood samples that can be used for test development, calibration, and validation. By providing samples in a single, organised study, this research aims to make the development of new diagnostic tests quicker and more efficient. The tests developed may relate to a range of health conditions, such as heart disease, diabetes, infections, or kidney disease.

Who can participate?
Patients aged 18 years and over attending the Golden Jubilee National Hospital for clinical care

What does the study involve?
Participants will be approached by a nurse and given information about the study. Those who are interested will receive a Participant Information Sheet explaining the purpose of the study, what taking part involves, and how samples and data will be used.
If participants agree to take part and provide written consent, an additional blood sample will be collected from their arm at the same time as routine blood tests, using standard procedures. In some cases, participants may also be asked to provide a small finger-prick blood sample, similar to a blood glucose test.
The blood samples may be tested immediately at the hospital or stored and transferred to another laboratory for analysis. Samples may be used as whole blood or processed into plasma or serum. No changes are made to the participant's usual clinical care.

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants from taking part in this study. However, the

research may help improve the development of future diagnostic tests, which could benefit patients and the NHS in the future.
The risks are low and are similar to those associated with routine blood sampling, such as mild discomfort, bruising, or rarely infection at the sampling site.

Where is the study run from?
Golden Jubilee National Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2025 to December 2030

Who is funding the study?
JEMMDx Ltd (UK)

Who is the main contact?
Dr Jayne Ellis, jayne@jemmdx.com

Contact information

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Scientific, Public

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Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
354396

Central Portfolio Management System (CPMS)
67102

Study information

Scientific Title
Diagnostic advancement through specimen collection research and testing (DART)

Acronym
DART

Study objectives
Provision of specimens for research, development and evaluation of diagnostic test devices providing results comparable to the approved gold standard reference methods. Ultimately with the aim of improving outcomes by clinicians and subjects being able to monitor health conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2025, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)2071048285; cambridgecentral.rec@hra.nhs.uk), ref: 25/EE/0120

Primary study design
Observational

Secondary study design
Specimen collection for diagnostic test research and development

Study type(s)

Health condition(s) or problem(s) studied
Patients presenting with symptoms of the areas of interest embolisms, infection or inflammation, cardiometabolic (includes heart failure, cardiovascular disease, myocardial infarction, diabetes) and renal cohorts

Interventions
Collection of venous and capillary blood samples from subjects with disease areas of interest (including but not limited to embolisms, infection or inflammation, cardiometabolic (including

heart failure and acute coronary syndromes) and renal cohorts) to develop, optimize and evaluate performance of diagnostic measuring biomarkers in the specimens and comparing results to the laboratory reference method. All subject data is anonymized.

Intervention Type
Other

Primary outcome(s)
1. Blood (plasma or serum) biomarkers related to one or more of the following conditions: embolism, cardiometabolic diseases, inflammation, infection, renal issues and others, measured using novel diagnostic devices and compared to a laboratory reference method for accuracy at a single timepoint

Key secondary outcome(s))

Completion date
30/12/2030

Eligibility

Key inclusion criteria
1. 18 years of age or over
2. Willing and able to provide written informed consent and comply with study procedures
3. Subjects attending a definitive care team with research capabilities which has been enrolled in this collection study
4. The subject must present as one of the following cohorts:
Group A – Embolism Cohort:
Subjects presenting with symptoms indicative of thromboembolic events
Group B – Infection or Inflammation Cohort:
Subjects presenting with symptoms indicative of infection or inflammatory disorders
Group C – Cardiometabolic Cohort:
Subjects presenting with symptoms indicative of heart conditions such as cardiovascular disease, heart failure or acute coronary syndrome, or diabetes
Group D – Renal Cohort:
Subjects presenting with symptoms indicative of renal disorders
Group E – Other Cohort:
Subjects who are not eligible for any other groups

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. <18 years of age
2. Vulnerable populations deemed inappropriate for the study by the sites Principal Investigator
3. Subjects who have previously been enrolled in the study within the past 3 months and re-entry would breach the 24 ml and or 6 fingerstick maximums

Date of first enrolment
09/10/2025

Date of final enrolment
09/10/2030

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS National Waiting Times Centre Board
Agamemnon Street
Clydebank
Scotland
G81 4DY

Sponsor information

Organisation
JEMMDx Ltd

Funder(s)

Funder type

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available