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A bedside evaluation of a marker of heart injury in the blood

Submission date	Recruitment status	[ ] Prospectively registered
01/06/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/07/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/12/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When patients are admitted to a hospital with suspected heart attacks they have numerous blood tests over a number of hours before the diagnosis of a heart attack (acute myocardial infarction) can be excluded. The tests measure cardiac troponin, a marker of heart injury. Over the last decade, high-sensitivity cardiac troponin assays have been widely implemented and, by precisely detecting small concentrations of cardiac troponin, allow much faster diagnosis of heart attacks than was previously possible.

Point of care high-sensitivity cardiac troponin assays, which sensitively measure cardiac troponin levels within minutes at the patient's side, are now available. In this study, we will test the accuracy of new point-of-care high-sensitivity cardiac troponin assays for the diagnosis of acute myocardial infarction in the Emergency Department (ED).

Who can participate?
Adults presenting to the ED with chest pain or similar symptoms

What does the study involve?
In this study, we will ask consenting patients if they would donate blood samples for analysis in this research. We will draw blood on arrival and 1 hour later. The blood will be tested for levels of cardiac troponin using the new point of care assays. We will also collect data about the patient's symptoms and past history to see if using established risk scores and decision aids alongside the new troponin assays will improve diagnosis. Patients will undergo standard clinical assessment as part of the routine care and we will check if they have had any further cardiac events over the next 30 days by checking medical records +/- contacting the patient or their general practitioner, and an expert panel will determine whether the final diagnosis was acute myocardial infarction.

What are the possible benefits and risks of participating?
In some cases, the additional blood tests may cause some discomfort. In a small minority of cases, this may be complicated by bruising or discomfort at the site of venepuncture. Risks will be minimized by ensuring that trained members of staff undertake venepuncture. There is no direct benefit to their clinical care at the time of participating in the research. However, should

the patient develop similar symptoms in the future, they may stand to benefit from the advances in diagnostic technology that may arise from this study.

Where is the study run from?
Manchester Royal Infirmary

When is the study starting and how long is it expected to run for?
December 2021 to December 2023

Who is funding the study?
Siemens Healthineers (Germany)

Who is the main contact?
Professor Richard Body, best.2study@mft.nhs.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
303373

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 303373, CPMS 51536

Study information

Scientific Title

The second bedside evaluation of sensitive troponin (BEST-2) Study

Acronym
BEST-2

Study objectives
In patients presenting to the Emergency Department (ED) with suspected acute coronary syndromes (ACS), what is the diagnostic accuracy of the Siemens Atellica VTLi high-sensitivity cardiac troponin I assay when used, with and without decision aids that take account of a patient' s history and ECG, at the time of presentation and 1 hour later, for the target condition of acute myocardial infarction (AMI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/02/2022, East Midlands-Derby Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44(0)207 1048211; derby.rec@hra.nhs.uk), ref: 22/EM/0005

Study design
Multicentre observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Acute Coronary Syndromes

Interventions
An additional blood sample will be taken at the same time as routine sampling for the majority of patients. Some patients may require blood to be drawn after they have had routine blood samples. To minimise discomfort, where possible we will draw the sample from an indwelling intravenous cannula using aseptic technique. Participants will be followed up 30 days later via medical records and general practitioner, but possibly also patient contact.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Siemens Atellica VTLi high-sensitivity cardiac troponin I assay

Primary outcome(s)

Diagnostic accuracy of the Siemens Atellica VTLi high-sensitivity cardiac troponin I assay, measured on arrival in the emergency department and 1 hour later using thresholds below the 99th percentile upper reference limit, for the target condition of acute myocardial infarction

Key secondary outcome(s))
1. Incidence of major adverse cardiac events (MACE, cardiovascular death or AMI occurring within 30 days of enrolment), as measured by a review of medical records and/or GP questionnaire at 30 days
2. Incidence of coronary revascularization, as measured by review of medical records and/or GP questionnaire at 30 days
3. All-cause mortality, as measured by review of medical records and/or GP questionnaire at 30 days
4. Length of hospital stay, as measured by review of medical records and/or GP questionnaire at 30 days

Completion date
07/12/2023

Eligibility

Key inclusion criteria
1. Aged 18 years or more
2. Presenting to the emergency department with a primary complaint of pain or discomfort in the chest, epigastrium, arm(s), jaw, neck or throat, which the treating clinician suspects may have been caused by an acute coronary syndrome

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
720

Key exclusion criteria
1. Overt ST-elevation myocardial infarction (STEMI) requiring immediate referral for coronary revascularization
2. Another reason requiring hospital admission, even if the diagnosis of acute coronary syndrome is excluded (e.g. arrhythmia, gastrointestinal bleeding, sepsis)

3. No symptoms in the previous 12 hours
4. No capacity, or unwillingness, to provide written informed consent

Date of first enrolment
01/07/2022

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford

United Kingdom
OX3 9DU

Study participating centre
St Georges Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Paisley
United Kingdom
PA2 9PN

Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Siemens Healthineers

Alternative Name(s)
Siemens Healthineers AG

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Richard Body richard.body@mft.nhs.uk. Anonymised data detailing the results of the index test and adjudicated final diagnosis will become available following peer-reviewed publication of the primary manuscript for 10 years. Anonymised data will be available upon request for anyone with an academic, non-commercial interest, subject to permission from the funder (Siemens Healthineers). Personal or potentially identifiable data and commercially sensitive data cannot be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No