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Suspected cardiac chest pain in the emergency department

Submission date
21/04/2023

Recruitment status
No longer recruiting

Registration date
04/05/2023

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study will examine Emergency Department (ED) rule-out strategies for patients presenting with suspected cardiac chest pain. The study aims to understand how the use of blood tests and investigation strategies impacts a patient's time in the ED. The study will also collect data on the final diagnoses of patients presenting to the ED with suspected cardiac chest pain, whether that be cardiac or non-cardiac in origin.

Who can participate?
Patients over the age of 18 years old attending the ED who require testing for suspected cardiac chest pain

What does the study involve?
The study involves no change to the tests carried out or treatment received. It involves the collection of information that is recorded as part of the routine care provided to the relevant patients.

What are the possible benefits and risks of participating?
There is no direct benefit to participants from their data being included in this study. There is potential for future benefit if the findings are used to better inform the healthcare delivery or management and investigation of suspected cardiac chest pain.

As there is no change to tests or treatment as part of the study, and all information used is recorded as part of routine clinical care, there is no additional risk to participants in terms of the care they receive. There are small privacy and confidentiality risks that are addressed in the manner in which data is collected and stored.

Where is the study run from?
The study is sponsored by North Bristol NHS Trust (UK). It is led by the UK Royal College of Emergency Medicine (RCEM) Trainee Emergency Research Network (TERN). The chief investigator for the study is based at the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
March 2022 to May 2023

Who is funding the study?
Royal College of Emergency Medicine (RCEM).

Who is the main contact?
Dr Fraser Birse (TERN Fellow), tern@rcem.ac.uk

Study website
https://ternresearch.co.uk/acs-ed

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316000

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53789, IRAS 316000

Study information

Scientific Title
Acute coronary syndrome rule-out strategies in the emergency department: An observational evaluation of current UK practice & clinical effectiveness

Acronym
ACS:ED

Study objectives
This is an observational study. Our overall aim is to establish the clinical effectiveness of different ACS investigation strategies across EDs in the UK, the epidemiology of ACS across the UK, and the different investigation strategies these EDs use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2022, Health and Care Research Wales (4, 15-19 Cowbridge Road East, Castlebridge, Cardiff, CF11 9AB, UK; +44 (0)29 2023 0457; Wales.REC3@wales.nhs.uk), ref: 22/WA/0247

Study design

Prospective multi-centre observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ischaemic heart diseases

Interventions
This study is a prospective multi-centre observational study that will be conducted across a ten-week period starting in March 2023. Patients will be actively recruited over a period of 7 days chosen by each site within a six-week window. A cross-sectional survey will also be administered to all recruiting hospitals collecting data on their local ACS rule-out strategies.

Participants: Consecutive adult (18 years or above) patients presenting to the ED with suspected cardiac chest pain who trigger testing to diagnose or exclude a suspected cardiac cause for their chest pain will be recruited. Patients with another medical condition requiring hospital admission, prisoners presenting to ED, non-English speakers for whom the translation is unable to be offered, and those with a clear non-ACS cause at presentation will be excluded.

Data collection: Patients will be identified prospectively but, depending on resource availability, may be collected retrospectively. Data collection will be performed by clinicians or research teams where these are present. To maximise the generalisability of the study but minimize the administrative burden, the team decided to use an opt-out consent process to facilitate recruitment into the trial. Demographic data and pathway-specific parameters will be collected at the point of clinical review on digitised case report forms (CRF). Research nurse or clinician follow-up using clinical notes or electronic health records will be conducted to document reference standard ED diagnosis and clinical outcome including acute myocardial infarction (AMI). Patient data collected will focus on pathway performance, including patient demographics, length of stay in ED +/- observation ward, ED disposition and discharge diagnosis, as well as information on biochemical markers and patient-risk category for ACS as assessed by the risk-stratification strategy used at each ED. Data will be collected separately from each site about their use of biochemical assays, reference ranges, use of ACS rule-out strategy and pathway for investigation of these patients. After the patient has been discharged from the ED or observation unit subsequent relevant investigations performed within 28 days will be followed up.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. Index acute myocardial infarction rate measured using coded diagnosis and assessment of troponin results and ECG changes at discharge from hospital
2. Length of stay in the emergency department +/- observation ward measured in minutes at presentation/baseline
3. ACS risk stratification strategy used, and patient risk category measured using the risk category as per stratification tool used at each site eg. very low/low/moderate/high at presentation/baseline

Secondary outcome measures
1. Time to be seen by the treating clinician measured in minutes at presentation/baseline
2. Emergency department disposition measured at the discharge destination at discharge from the emergency department
3. Discharge diagnosis measured using coded discharge diagnosis at discharge from hospital

Overall study start date
01/03/2022

Completion date
29/05/2023

Eligibility

Key inclusion criteria
1. All adult patients (> = 18 years of age) presenting to the ED with chest pain who trigger testing to rule-in or rule-out a cardiac cause

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 5460; UK Sample Size: 5460

Total final enrolment
8621

Key exclusion criteria
1. Patients with another medical condition requiring hospital admission
2. Clear non-ACS cause at presentation
3. Prisoner presenting to ED
4. Non-English speakers where translation is unable to be offered

Date of first enrolment
13/03/2023

Date of final enrolment
23/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Bristol NHS Trust [Lead]
Southmead Hospital
Southmead Road
Westbury-on-trym
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Sponsor information

Organisation
North Bristol NHS Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
University/education

Funder Name
Royal College of Emergency Medicine

Alternative Name(s)
RCEM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results from this study will be submitted for publication in leading journals and to national conferences for presentation. We will aim to do this by May 2024. The Trainee Emergency Research Network's (TERN's) work with RCEMLearning has generated a focal point for knowledge dissemination in the UK. Using social media and TERN's email list, TERN will publish a multitude of blogs, infographics and podcasts to supplement a publication, which will be hosted on RCEMLearning.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, REDCap, https://www.project-redcap.org/. The type of data stored

will be: Date of birth; Ethnicity; Sex; Length of stay; Investigation results; and, Discharge diagnosis. The process for requesting access is to contact the central study team via tern@rcem.ac.uk. Timing for availability to be decided if any requests are received. This study is using opt-out consent.
Data is pseudo-anonymised at the point of entry to the central study database.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.4	31/01/2023	26/04/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		18/06/2025	24/06/2025	Yes	No