ISRCTN86184521 https://doi.org/10.1186/ISRCTN86184521

The LoDED study – safe & rapid chest pain management

Submission date
09/04/2018

Recruitment status
No longer recruiting

Registration date
23/04/2018

Overall study status
Completed

Last Edited
31/08/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
When someone arrives in Accident and Emergency (A&E) with chest pain, it is often hard for doctors to tell if the pain is due to a heart attack. Most patients have to wait in hospital, having two blood tests taken a few hours apart, before a heart attack can be ruled out. Only 1 in 10 of these patients have actually had a heart attack - most have conditions like heartburn that aren't serious. Ruling out heart attacks faster would reassure patients earlier and reduce time spent in hospital. Around 2 million people a year in Britain come to A&E with chest pain. Finding a way for them to be discharged earlier would mean hospitals would be under less pressure. A blood test, called high-sensitivity troponin, may be used to rule out heart attacks using just one blood sample shortly after a patient arrives in A&E. This test measures low levels of heart muscle damage in the blood. The aim of this study is to find out whether this single test works in everyday practice.

Who can participate?
Patients aged 18 and over with chest pain, arriving at one of seven participating A&Es

What does the study involve?
Participants are randomly allocated to one of two groups. One group is discharged after one blood test, if no heart damage is found. The other group have two blood tests as usual. The groups are compared to see how many patients can be discharged within 4 hours, and to see whether the new method saves hospital resources and if patients are reassured when discharged earlier.

What are the possible benefits and risks of participating?
If the participant feels well and they have no further chest pain, they may be discharged after one blood test rather than two and this may allow patients to go home earlier in future. This may be of benefit to the participant. Through previous research, it is known that ruling out heart attacks using a single blood test is likely to be as safe as routine care. Therefore, the risks of missing a heart attack are very low. However, this method is new and still not routine care in most hospitals and the researchers will carefully monitor that it is safe during the study.

Where is the study run from?
1. North Bristol NHS Trust (UK)
2. Royal United Hospitals Bath NHS Foundation Trust (UK)
3. Royal Devon and Exeter NHS Foundation Trust (UK)
4. Plymouth Hospitals NHS Trust (UK)
5. University Hospital of Wales (UK)
6. University Hospitals of Leicester NHS Trust (UK)
7. Royal Berkshire NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to April 2019 (updated 17/06/2019, previously: October 2019)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Sarah Campbell
sarah.campbell@plymouth.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Sarah Campbell

Contact details
Peninsula Clinical Trials Unit
Room N16
ITTC Building 1
Plymouth Science Park
Davy Road
Plymouth
United Kingdom
PL6 8BX
+44 (0)1752 430 392
sarah.campbell@plymouth.ac.uk

Additional identifiers

Protocol serial number
37566

Study information

Scientific Title
Randomised controlled trial of the LoDED (Limit of Detection of Troponin and ECG Discharge) strategy versus usual care in adult chest pain patients attending the Emergency Department

Acronym
LoDED

Study objectives
When someone arrives in Accident and Emergency (A&E) with chest pain, it is often hard for doctors to tell if the pain is due to a heart attack. Most patients have to wait in hospital, having two blood tests taken a few hours apart, before a heart attack can be ruled out. Only 1 in 10 of these patients have actually had a heart attack - most have conditions like heartburn that aren't serious. Ruling out heart attacks faster would reassure patients earlier and reduce time spent in hospital. Around 2 million people a year in Britain come to A&E with chest pain. Finding a way for them to be discharged earlier would mean hospitals would be under less pressure. A blood test, called high-sensitivity troponin, may be used to rule-out heart attacks using just one blood sample shortly after a patient arrives in A&E. This test measures low levels of heart muscle damage in the blood. The aim of this study is to find out whether this single test works in everyday practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Frenchay Research Ethics Committee, 11/04/2018, ref: 18/SW/0038

Study design
Randomised; Interventional; Design type: Diagnosis, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chest pain

Interventions
After written consent has been obtained, participants will be randomised to be evaluated using either the existing rule-out strategy used in study centres (control) or the LoDED strategy (intervention) in a 1:1 ratio. The Peninsula Clinical Trials Unit (PenCTU), in conjunction with the study statistician, will provide web-based randomisation, stratified by centre and minimised by age and gender. Appropriate staff at all sites, as delegated by the PI, will be provided with log-in details for the study website.

Control arm
Participant admitted or discharged based on usual rule-out strategy operating in that hospital (varies between recruiting centres). Usual care includes ECG on arrival and usually two hs-troponin tests. All centres take the first sample at presentation, but the minimum time delay between the two samples varies.

Intervention arm
(LoDED Strategy) Participant discharged after a single hs-troponin test at presentation to ED if hs-troponin is below the LoD. Participant not fulfilling discharge criteria will have a second hs-troponin test after 1-6 hours as per usual care.

For all participants, individual trial participation will be from the time of written informed consent until 30 (+5) days after initial ED attendance. The groups will be compared to see how many patients can be discharged within 4 hours, and to see if the new method saves hospital resources and if patients are reassured when discharged earlier.

Intervention Type
Other

Primary outcome(s)
Successful early discharge, defined as discharge from hospital within four hours of arrival, without a Major Adverse Cardiac Event (MACE) occurring within 30 days of ED attendance

Key secondary outcome(s))
1. Length of ED/ED Observation Unit (EDOU) stay, measured in hours. Discharge from the ED within four hours of attendance will be measured using electronic patient tracking systems in use at all study sites, according to the time the patient left the ED (including ED observation units). In the event that a participant is transferred from the ED, to an observation unit or inpatient bed within four hours of attendance and subsequently discharged, length of stay (minutes/hours) will be calculated from electronic patient records and tracking systems
2. Hospital admission and subsequent length of stay - time of admission and discharge to hospital – calculated from electronic patient records and tracking systems
3. Incidence of MACE, within 30 days of the index ED attendance – will be recorded on the SAE form, by the local ED Principal Investigator or designee with reference to relevant clinical information and responses to 30 day follow-up telephone assessments
4. Comparative costs. Resource use data to be collected from all participants with an initial hs-troponin below the LoD, at 30 (+5) days by telephone/by e-mail and electronic patient records (to include GP records where available) will include: use of health services in the last 30 days, length of any subsequent hospital stays (since initial visit to ED); hospital tests carried out during any subsequent hospital admissions, and time off work in the last 30 days. Participants with an initial hs-troponin below the LoD (irrespective of group allocation) will also be asked to complete a second EQ-5D health status questionnaire during their 30-day follow-up
5. Patient satisfaction (quantitative survey) measured using a bespoke written patient satisfaction questionnaire upon discharge from the ED
6. Acceptability to patients (qualitative methodology): up to 25 participant interviews will be conducted by phone using a topic guide to explore experiences of the participant’s stay in ED, any concerns or anxieties they might have

Completion date
03/04/2019

Eligibility

Key inclusion criteria

1. Age ≥18 years
2. Presenting to ED with chest pain and triggering the chest pain investigation pathway i.e. treating clinician intends to perform investigation to rule out a cardiac cause
3. Peak symptoms occurred <6 hours prior to presentation to the ED

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
632

Key exclusion criteria
1. ST-elevation myocardial infarction or ischaemic ECG (new T wave inversion > 3mm or ST depression > 1mm) as judged by the treating clinician
2. Clear non-ACS cause for chest pain found at presentation (e.g. pulmonary embolism, pneumonia, aortic dissection)
3. Initial hs-troponin result known to the treating clinician
4. Hospital admission indicated due to other medical/social reasons
5. Chest pain due to arrhythmia (new-onset atrial fibrillation, atrial flutter, sustained supraventricular tachycardia, second-degree or complete heart block, or sustained or recurrent ventricular arrhythmias)
6. Unable to provide written informed consent (lacks capacity)
7. Unwilling to provide written informed consent
8. Pain too severe to provide written informed consent
9. Follow-up will be impossible i.e. lives abroad or no fixed abode
10. Previous inclusion in the study
11. Prisoners
12. Pregnancy
13. Pre-existing renal failure requiring dialysis

Date of first enrolment
04/06/2018

Date of final enrolment
04/03/2019

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Plymouth Hospitals NHS Trust
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre

University Hospital of Wales
Heath Park Way
Cardiff
United Kingdom
CF14 4XW

Study participating centre
University Hospitals of Leicester NHS Trust
Gwendolen House
Gwendolen Road
Leicester
United Kingdom
LE5 4QF

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0416-20012

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	21/05/2020	Yes	No
Results article	Patients' and health professionals' perceptions	09/12/2020	31/08/2023	Yes	No
Protocol article		02/10/2018	17/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes