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Triage Rule-out Using Sensitive Troponin (TRUST): Study of early risk-stratification of suspected cardiac chest pain and initiation of 1-hour high-sensitivity troponin testing in very low and low-risk Emergency Department patients

Submission date
05/01/2012

Recruitment status
No longer recruiting

Registration date
07/03/2013

Overall study status
Completed

Last Edited
05/09/2017

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims

Chest pain makes up a significant proportion of Emergency Department (ED) attendances. In fact, 6% of all presentations to UK EDs are due to chest pain which amounts to 700,000 patients per year UK-wide. Due to the potentially catastrophic consequences of a missed heart attack, both medically and legally, the majority of chest pain patients are admitted for further assessment. As a result, 25% of all acute medical admissions to hospitals are due to chest pain. 85% are subsequently shown not to have a final diagnosis of a heart attack. Since each chest pain admission costs on average £2500 this has a huge impact on NHS resources.

Current recommendations to rule out a heart attack are based upon the patient having a normal ECG (heart-tracing) and the absence of a protein in the blood called troponin, which is released when the heart muscle is injured. Troponin is currently measured between 6 and 12 hours from ED presentation. The majority of tests are normal but this wait leads to excessive patient anxiety, unnecessary prolongation of hospital stay and ED overcrowding. The development of a diagnostic pathway that allows more rapid assessment of patients with chest pain and prevents unnecessary hospital admission will have a profound benefit on healthcare services.

This study aims to test the safety of a novel diagnostic pathway for the rapid assessment of patients with chest pain that allows the rapid rule-out of heart attack. This pathway is based upon the very recent development of a new blood test that detects heart injury called the high-sensitivity Troponin (hs-Tn) assay. The use of hs-Tn has been shown to be accurate in the detection of heart attacks but whether it is also effective in the rapid rule-out of heart attacks has yet to be established. Our Accelerated Diagnostic Pathway (ADP) has been designed to identify those patients at very low risk of having heart-related pain. This group of patients is suitable for early discharge and does not need hospital admission. We estimate that our protocol will demonstrate a safe reduction in the number of hospital admissions due to chest

pain by at least 20%. This would represent a significant saving for an average-sized district general hospital.

Who can participate?
Patients between the ages of 18 and 79 who present to Poole Hospital Emergency Department with chest pain that the treating doctor thinks may be related to the heart and are being admitted to a ward for observation and further tests will be invited to take part in the study. The clinical treatment of those who participate will not change in any way.

What does the study involve?
1200 patients with suspected cardiac chest pain will be recruited over a 12-month period, commencing from November 2012. We ask that an extra 2.5 ml (half-a-teaspoon) of blood is given during routine admission blood testing for use in research. All patient details will be handled in confidence, with patient names being replaced by a code number that will be used on all documents for the study. Each particpants' heart attack risk will be assessed using an Accelerated Diagnostic Protocol. Within this, a very low risk patient will be identified on the basis of a normal ECG, a low score on a questionnaire-based risk assessment tool and a low hs-Tn blood level taken within the first hour of arrival in the ED. The very low risk of heart attack in this group will be confirmed by the lack of major adverse cardiac events within 30 days of follow-up.

What are the possible benefits and risks of participating?
If the Accelerated Diagnostic Pathway (ADP) is able to identify these patients correctly it would indicate that these patients are suitable for early discharge. This may pave the way for new methods to improve patient care, reduce hospital overcrowding and reduce costs to the NHS.

Where is the study run from?
Poole Hospital Emergency Department, Dorset, UK
The study is being funded by Bournemouth University and Poole Hospital Cardiology Research Funds.

When is the study starting and how long is it expected to run for?
Patients will be recruited over a 12-month period, commencing from November 2012.

Who is funding the study?
South Central Strategic Health Authority (UK) - Service Improvement Fellowship

Who is the main contact?
Dr Edward Carlton
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
An Accelerated Diagnostic Pathway incorporating the Modified Goldman Criteria and 1-hour high-sensitivity troponin testing to identify low-risk Emergency Department patients with chest pain who may be suitable for immediate discharge

Acronym
TRUST

Study objectives
A 1-hour high sensitivity troponin level of <14ng/l will allow early safe discharge of patients presenting to the Emergency Department with chest pain of suspected cardiac origin and a very low or low clinical risk (assessed using a modified Goldman Score).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Frenchay Regional Ethics Committee, 30/05/2012, ref: 12/SW/0133

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Chest pain

Interventions
All patients with chest pain of suspected cardiac origin and a normal ECG on arrival in the Emergency Department will be screened to undergo blood sampling for high-sensitivity Troponin testing within 1 hour of arrival, at the same time as routine admission blood testing. Although the main focus of the study is to analyse those patients who are very low or low risk, all patients will be troponin tested, no matter which risk category they belong to. This will allow subsequent analysis of patients who are 'positive' for the diagnostic screening process. Without this data the study will lack a full set of diagnostic statistics (to include specificity and positive predictive values).

ECG findings will subsequently be analysed by study investigators who may then exclude the patient from the study if an abnormality is found during subsequent analysis.

As part of the study protocol, clinical nursing staff or healthcare assistants will also be asked to complete a Modified Goldman risk assessment score, using standard variables from the history and examination. Treating clinicians will be blinded to the results. All patients currently undergo Goldman risk assessment by treating physicians as part of standard care. Nursing risk assessment will be compared to physician risk assessment for accuracy by the study researchers.

Patients will have ongoing investigations, onward referral and treatment at the discretion of the treating physician, who will be blinded to the early hsTnT result. Upon discharge from hospital all patients will be asked to complete a questionnaire to establish whether a prolonged period of admission and observation is required in patients presenting with chest pain.

Data collection will be carried out prospectively by the research team using the Symphony ED or hospital electronic patient record and GP records to allow follow-up of major adverse cardiac event (MACE) at 30 days. There will be recording of age-related co-variates, risk factors, medications and other key clinical variables according to the data dictionary.

Classification of all final diagnosis including cases of ACS and adverse events will be done by blind independent review of relevant data.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The proportion of very low or low-risk patients (established using the modified Goldman risk score) with a troponin blood result of <14ng/l at 1 hour with no major adverse cardiac events at 30 days after initial presentation (including initial hospital attendance)

Secondary outcome measures
1. The accuracy of Emergency Department nursing staff risk assessment using the modified Goldman risk score to determine very low/low clinical risk in comparison with doctor risk assessment using the same score
2. Patient opinion as to whether a prolonged period of admission and observation is required for reassurance in this low-risk group

Overall study start date
18/07/2012

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Consenting adults (age 18-79) presenting to the Emergency Department with at least 5 minutes of chest pain (or discomfort) suggestive of acute coronary syndromes for whom attending clinicians are planning further assessment with delayed (6 hour) troponin testing
2. Possible symptoms suggestive of acute coronary syndromes include acute chest, epigastric, neck, jaw or arm pain; or chest discomfort or pressure without an apparent non-cardiac source.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
79 Years

Sex
Both

Target number of participants
1200

Key exclusion criteria
1. Age <18 or >79
2. Patients with ischaemic initial electrocardiogram (ECG) or ST-elevation infarct
3. Atypical symptoms (fatigue, nausea, vomiting, diaphoresis, faintness and back pain) in the absence of chest pain or discomfort

4. An alternative cause of chest pain is suspected at presentation (e.g. pulmonary embolus, dissection, pneumothorax)
5. Refusal of patient consent
6. Renal failure requiring dialysis
7. Unable to speak English language
8. Follow-up will be impossible
9. Trauma with suspicion of myocardial contusion
10. Another medical condition that necessitates hospital admission
11. Prisoners
12. Pregnancy

Date of first enrolment
01/11/2012

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Poole Hospital
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Government

Funder Name
South Central Strategic Health Authority (UK) - Service Improvement Fellowship

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No
Results article	results	01/10/2015		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	results	01/02/2016		Yes	No
Results article	results	01/04/2018		Yes	No