Pre-hOspital evaluation of chest Pain patients with sUspected non ST-segment eLevation myocARdial infarction using the HEART-score with a Troponin point-of-care test

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Co-primary Objectives:1. To assess the interobserver agreement between the pre-hospital HEART-score calculated by ambulance personnel and the in-hospital HEART-score calculated by emergency physicians.2. To evaluate the diagnostic performance of a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON49607

Source
ToetsingOnline

Brief title
POPULAR HEART

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
acute coronary syndrome, chest pain

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds

Intervention

Keyword: acute coronary syndrome, HEART score, myocardial infarction, troponin

Outcome measures

Primary outcome

Main study parameters/endpoints:

1. HEART-score agreement (interobserver variability between pre-hospital and

in-hospital HEART-score assessment) (primary objective)

2. Final diagnosis of NSTE-ACS at discharge

3. Myocardial infarction at discharge

Secondary outcome

Secondary study parameters/endpoints:

4. Composite endpoint (cardiovascular mortality, myocardial infarction, urgent

revascularisation) at 30 days

5. Angina frequency and stability, physical limitations, treatment

satisfaction, quality-of-life, cardiac anxiety and depression (SAQ, PHQ-4)

Study description

Background summary

Overcrowding in the emergency department is an increasing problem in hospitals worldwide. Currently, all patients with acute chest pain without ST-segment elevation on the electrocardiogram (ECG) are transported to the emergency department in order to rule in or rule out a myocardial infarction.
Point-of-care Troponin (POC cTn) testing in combination with a well

investigated risk stratification tool (HEART-score) used in the ambulance may contribute to an earlier diagnostic process of ruling in or ruling out myocardial infarctions and subsequently reduce unnecessary hospital admissions, total admission time and costs. However, the applicability of the POC cTn and the HEART-score in the pre-hospital setting remains unclear.

Study objective

Co-primary Objectives:
1. To assess the interobserver agreement between the pre-hospital HEART-score calculated by ambulance personnel and the in-hospital HEART-score calculated by emergency physicians.
2. To evaluate the diagnostic performance of a strategy based on a pre-hospital HEART-score (with POC cTn testing) or combined with an adjuvant single hs-cTn test at the emergency department to rule-in or rule-out acute coronary syndrome (ACS).
3. To evaluate the diagnostic performance of (serial) POC cTn testing or combined with hs-cTn testing compared to (serial) hs-cTn testing to rule-in or rule-out MI.
4. To investigate the feasibility of using the pre-hospital HEART-score and POC cTn in the 0/1 hour algorithm to rule-out ACS.
Secondary Objectives:
5. To evaluate the occurrence of major adverse cardiac events (MACE) in all included patients with a follow up time of 30 days from first medical contact.
6. To evaluate the patient reported outcome measures (PROMs) in all chest pain patients transported to the hospital at baseline and at 30 days
7. To perform a cost-analysis of an early diagnostic strategy using the pre-hospital HEART-score

Study design

Study design: A prospective, observational, multicentre study

Study procedures: The HEART-score and the POC cTn will be calculated in all included patients in the pre-hospital phase. Simultaneously, a venous blood sample will be drawn from the venous access site for later hs-cTn testing. Outcomes of any pre-hospital study measurements (i.e. pre-hospital POC cTn results or calculated pre-hospital HEART-scores) will not affect usual care. According to current practice, all patients will be transported to the hospital for further evaluation.

At the emergency department (ED) all included patients will undergo regular hs-cTn testing and HEART-score assessment performed by emergency physicians (standard care), and an additional venous bloodsample will be drawn for cTn measurements. Physicians at the ED are blinded to the outcomes of the POC cTn tests and pre-hospital HEART-scores.

Follow-up: Total follow-up duration is 30 days after initial presentation. Other demographic and clinical parameters at baseline will be taken into account.

Study burden and risks

All patients will receive a POC cTn test performed by ambulance personnel and a standard care highly-sensitive troponin at the emergency department. In all patients, an extra venous blood sample will be drawn from the venous access site in the pre-hospital phase and venous blood sample will be drawn next to routine blood testing at the emergency department. Besides the minimal risks of performing a POC finger prick test, no other risks are involved with study participation. All patients will be asked to fill in quality-of-life questionnaires (i.e. SAQ, PHQ-4) at baseline and at follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- All out-of-hospital chest pain patients visited by an ambulance
- Transportation to a hospital with working diagnosis non ST-segment elevation acute coronary syndrome
- Age >= 18 years

Exclusion criteria

• Comatose state
• Cognitive impairment
• Pregnancy
• Hemodynamic instability or shock
• No pre-hospital 12-lead ECG performed or available
• Electrocardiographic ST-segment elevation in the prehospital phase
• An obvious non-cardiac cause for the chest complaints (trauma, pneumothorax, pneumonia, etc.)
• Suspicion of aortic dissection or pulmonary embolism

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2020
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71897.100.19