Hollands-midden Acute Regional Triage - cardiology (HART-c): point-of-care high-sensitivity cardiac Troponin I study

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To determine the effectiveness of the HEART (History, Electrocardiogram (ECG), Age, Risk factors, Troponin) score with POC hs-cTnI testing by ambulance nurses in safely ruling out ACS and increasing the number of patients left at home after...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON53852

Source
ToetsingOnline

Brief title
HART-c: POC hs-cTnI study

Condition

- Coronary artery disorders

Synonym
heart infarction, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: RAVHM

Intervention

Keyword: Cardiology, Point-of-care, Triage, Troponin

Outcome measures

Primary outcome

Phase 1 compares analytical performance of the POC device to conventional cTnT in the central laboratory. In phase 2 HEART scores will be compared between intervention and control.

The main study parameter in phase 3 is the percent change in number of patients left at home after ambulance nurse consultation.

Secondary outcome

Secondary endpoints are the occurrence of Major Adverse Cardiac Events (MACE), defined as death, ACS or percutaneous coronary intervention (PCI) 6 weeks after ED assessment. Furthermore (diagnostic) performance of POC device, sensitivity and specificity of the HEART - and HEAR (HEART score without Troponin measurement) score will be assessed. Furthermore a 'delta' POC hs-cTnI will be assessed which might lead tot faster time-to-diagnosis.

Study description

Background summary

Emergency departments (EDs) are increasingly overcrowded leading to worse patient outcomes and increased healthcare costs. Chest pain is one of the main reasons for ED evaluation. However, over 80% of chest pain referrals are discharged on the same day after ruling out acute cardiovascular disease. Improved prehospital triage for safe rule-out of acute coronary syndrome (ACS) by ambulance nurses with a point-of-care (POC) high-sensitivity (hs) cardiac

Troponin I (cTnI) test, can aid in reducing unnecessary hospital referrals and thus reduce ED overcrowding.

Study objective

To determine the effectiveness of the HEART (History, Electrocardiogram (ECG), Age, Risk factors, Troponin) score with POC hs-cTnI testing by ambulance nurses in safely ruling out ACS and increasing the number of patients left at home after ambulance nurse consultation.

Study design

The study consists of three phases. Phase 1, a test-tube lab research, focuses on the analytical performance of the POC device. Phase 2 focuses on the clinical performance of the POC device in a controlled (in-hospital) setting. Phase 3 is a randomized controlled trial which divides chest pain patients in either intervention, HEART score with POC hs-cTnI by ambulance nurses and subsequent cardiologist consultation, and control, current standard of care with prehospital cardiologist consultation.

Intervention

In phase 1 patients presenting to the ED or CEU will have POC hs-cTnI tested by both CEU - or ED nurses and laboratory professionals. Analytical performances of the POC device will be compared to laboratory hs-cardiac Troponin T (cTnT) analyzed through the standard blood-draw by venepuncture. Phase 2 will have POC hs-cTnI tested by CEU - or ED nurses after which HEART scores will be calculated by treating physicians. HEART scores and clinical outcomes with the use of the POC device will be compared to standard care (HEART score including laboratory hs-cTnT). In phase 3 chest pain patients presenting to the regional EMS will be randomized in the ambulance to either intervention, POC hs-cTnI testing and subsequent HEART score calculation by ambulance nurse, or control, standard care including cardiologist consultation. After HEART score calculation by the ambulance nurse patients will either be left at home (HEART score <3 including low cTnI) or consulted to a triage cardiologist after which patients can be referred to one of the three regional hospitals or left at home. If patients are referred to the hospital, a second HEART score will be calculated upon arrival with POC hs-cTnI.

Study burden and risks

Low risk patients will have a POC assessment through fingerstick while they otherwise might not have been referred to the hospital. All other patients will benefit from faster and more accurate triage and have a lower risk of missed ACS. Over 80% of patients with chest pain are discharged from the ED without acute pathology on the same day as presentation. By selecting these low risk

patients in the prehospital setting they are spared a stressful and sometimes long ED visit.

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

Adults (aged 18 years or older) presenting to the EMS with chest pain suspected to be of cardiac origin with good understanding of Dutch or English language and capable of giving informed consent.

Exclusion criteria

Since the Siemens Healthineers Atellica VTLi is validated in chest pain experiencing chest pain for more than two hours, patients with chest pain since less than two hours will be excluded. Furthermore, the triage cardiologist is available on weekdays from 08.00-21.00. Patients presenting to the EMS paramedic outside of these hours are excluded from the study.
Patients with ST-elevation on first ECG, non-cardiac chest pain (e.g. traumata, pneumonia, pneumothorax) or in cardiogenic shock/out-of-hospital cardiac arrest will be excluded. Furthermore if the ambulance nurse estimates that the time from inclusion and consultation will lead to worse patient outcomes they can choose to present patients directly to the ED or CEU. If patients are presented to another hospital then the three regional participating hospitals they will also be excluded. Patients in detention centers or asylum centers at the moment of triage will be excluded from the study since follow-up is not possible for these patients.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2024
Enrollment:	1672
Type:	Actual

Medical products/devices used

Generic name:	fingerstick point-of-care high sensitive Troponin I assay
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-06-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-06-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-02-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL80873.000.22

Register	ID
Other	NL9475