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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28373

Source
NTR

Brief title
HARTc: POC hs-cTnI study

Health condition

Acute coronary syndrome

Sponsors and support

Primary sponsor: Department of Cardiology, Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

Phase 1:
Assessment of analytical performance specifications of POC hs-cTnI device as compared to the manufacturer’s claims. Benchmark of POC analytical performance compared to the “gold”

standard, i.e. conventional central lab hs cTnT test.
Phase 2:
Clinical comparability in HEART score of POC hs cTnI and standard clinical care
Phase 3:
Increase in number of chest pain patients left at home. Defined as the fraction of chest pain patients left at home in relation to all chest pain patients included

Secondary outcome

Secondary study parameter for phase 1 is the evaluation of operator variability by comparing ED - and clinical chemical lab results on the POC hs cTnI device.

Secondary study parameters for phase 2 are HEART scores using POC device, ‘standard care’ HEART scores and sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV) respectively. Furthermore MACE (death, ACS or PCI 30 days after assessment) rates will be assessed.

Secondary study parameters for phase 3 are HEART- and HEAR scores by ambulance nurses (and sensitivity, specificity, NPV, PPV respectively), MACE rates, (diagnostic) performance of POC device in the ambulance, time from ambulance nurse assessment to hospital, interhospital transfers after ED – or CEU assessment, final diagnoses (also for patients left at home), re-admission rates.

Study description

Background summary

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.

Study objective

Emergency departments (EDs) are increasingly overcrowded leading to worse patient

outcomes and increased healthcare costs (1-4). Chest pain is one of the main reasons for ED evaluation (5-7). However, over 80% of chest pain referrals are discharged on the same day (8-10). 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 design

Phase 1 will start in July 2022 and is expected to be completed in October 2022
Phase 2 will start in July 2022 and is expected to be completed in November 2022
Phase 3 will start in December 2022 and is expected to be completed in July 2023

Intervention

Phase 1:
In Phase 1, the analytical performance of the POC hs-cTnI test will be validated, especially at the low concentration end of cTnI, according to its intended use. In addition, non-inferiority of the hs cTnI POC device compared to central lab hs cTnT test, will be studied.

A fingerstick will be obtained and tested with a POC hs-cTnI device by the ED/CEU nurses to evaluate practical feasibility and imprecision on the ED/CEU. At the same time point, as is standard care, a blood sample will be obtained through venipuncture in the Leiden University Medical Centre (LUMC) by ED/CEU nurses. The drawn blood will be sent to the central laboratory of the LUMC and will also be tested on a POC hs-cTnI device by a qualified laboratory professional. Furthermore hs-cTnT will be analyzed on Roche Cobas analyzer, as per the standard clinical care pathway, to evaluate analytical imprecision.

Analytical imprecision will be evaluated at relevant IQC-levels during the entire familiarization study period. In addition, equivalence between fingerprick hs-cTnI results produced at the ED and venipuncture hs-cTnI results produced by a lab professional will be checked. Findings will be compared to the claims in the Instructions for Use. Analytical imprecision will also be benchmarked against the central laboratory hs- cTnT test results (5th generation from Roche). Cut-off values for clinical decision making, comparable to the cut-off values of hs-cTnT, will be obtained from these results.

For this validation, a total of 100 adult patients presenting to the ED or CEU of the LUMC with chest pain will be included.

Phase 2
In phase 2, the POC hs-cTnI test will be validated for non-inferiority on clinical performance as compared to the ‘standard care’; HEART score on the ED and CEU with laboratory hs- cTnT (Roche) and subsequent management. The treating physician will prospectively calculate the HEART score for both groups. This step aims to evaluate whether the POC hs-cTnI test demonstrates at least similar or better clinical performance as compared to the central laboratory hs- cTnT assay in chest pain patients.

On the ED risk stratification is performed by HEART score using hs-cTnT. Patients are

stratified into low (0-3), moderate (4-6) or high risk (7-10). MACE rates (death, ACS or PCI 30 days after assessment) are noted and compared between the two groups.

The laboratory hs- cTnT results produced in the LUMC will be used for clinical decision making. A HEART score will be calculated using the POC hs-cTnI fingerstick measurement obtained at the ED/CEU and using the POC hs-cTnI measurement analysed by the laboratory professional. In total three HEART scores are calculated per patient (standard, POC at the ED, and POC at the clinical chemical lab). Thereby practical feasibility and analytical imprecision are measured. The validation for clinical performance is based on 200 adult patients presenting to the ED or CEU of the LUMC with chest pain.

Phase 3:
In phase 3 chest pain patients will be included and randomized for prehospital clinical decision making using a POC hs-cTnI test in cardiac triage by ambulance nurses. They will be compared with the current standard of care, the HART-c method.

For the intervention all 34 ambulance are equipped with a POC hs-cTnI device. If a patient is seen by the ambulance nurse for EMS consultation they are randomly distributed in to 1) intervention with POC hs-cTnI device and 2) control with current standard of care.
For control patients have a calculated HEAR score, low- (HEAR 0-3) and moderate risk (HEAR 4-6) patients are consulted with the on-call cardiologist. High risk patients (HEAR 7-8) are sent to one of the three regional participating hospitals without cardiologist consultation.
The intervention consists of HEART score calculation, with POC hs-cTnI, by fingerstick by the ambulance nurse. If the patient is low-risk (HEART 0-3) and the measured cTnI is below the cut-off value given from phase 1 and 2, patients are left at home. Low-risk with high cTnI and moderate risk (HEART 4-6) patients are consulted with the on-call cardiologist. These patients can also be left at home if ambulance nurse and cardiologist see no further reason for hospital admission (see figure 1). Patients with high risk (HEART 7-10) will be sent to the hospital without cardiologist consultation. Ambulance nurses will be trained in calculating HEAR and HEART scores before onset of the study. The cardiologist is on-call on weekdays from 09.00 to 21.00. Outside of these hours patients cannot be included in the study. After cardiologist consultation, patients can be referred to one of three regional hospitals, one of which has the capability for PCI. High risk patients should preferably be sent to a PCI centre if intervention is deemed probable.

If patients are sent to one of the participating hospitals, in either group, blood draw is done by the ambulance nurse at the prehospital is scene, as is standard care as of this moment. This blood draw consists of three tubes; a gel tube, EDTA and a citrate tube which all will be provided to the healthcare professionals at the hospital. This prehospitally acquired blood improves time-to-diagnosis and treatment.

Phase 3 aims to assess the value for triage of cardiac patients using HEART score with POC hs-cTnI in the ambulance. Diagnostic accuracy (NPV, PPV, specificity and sensitivity) for rule out of ACS will be calculated. Using patient outcomes, the test characteristics will be assessed, with particular attention for NPV and sensitivity, and compared to standard care. An increase in the number of patients left at home is expected through improved pre-hospital triage, possibly also in moderate risk categories with low hs-cTnI after cardiologist

consultation.

Contacts

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Eligibility criteria

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

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2022
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9475

Register	ID
Other	METC LDD : follows

Study results