Clinical validation of novel point-of-care hs-cTn assay in identifying patients with myocardial infarction

Published: 09-11-2023
Last updated: 07-04-2024

Primary objective: To define the optimal cut-off concentrations for the POC hs-cTnI assay to rule out or rule in MI.Secondary objective: To determine and validate an assay-specific 0/1-h algorithm for ruling out and ruling in MI.

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

Summary

ID

NL-OMON53273

Source
ToetsingOnline

Brief title
POPULAR CONCORDANT

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: Ministerie van OC&W,Siemens

Intervention

Keyword: acute coronary syndrome, myocardial infarction, point-of-care, troponin

Outcome measures

Primary outcome

1. NSTE-ACS at discharge

2. Myocardial infarction at discharge

3. Safety endpoint: negative predictive value and sensitivity (POC hs-cTnI,

standard of care hs-cTn)

4. Accuracy endpoint: positive predictive value and specificity

Secondary outcome

5. Composite of all-cause mortality, MI and urgent revascularisation at 30 days

6. Length of stay (in hours)

7. Turnaround time POC and standard of care hsTroponin from blooddraw until

result

Study description

Background summary

Patients presenting with acute chest pain should be referred to the hospital promptly. In the absence of clear ST-segment elevations, evaluation with cardiac troponin (cTn) is necessary to rule out any myocardial injury. The introduction of high-sensitive cTn made it possible to reliably measure small amounts cTn concentrations, thereby increasing sensitivity and reducing time-to-diagnosis. Novel POC hs-cTn assays give the opportunity to use fingerstick sampling and a reduced analysis time of 8 minutes. To date, no cut-off concentration for rule-out of MI has been established for the POC hs-cTnI assay on the VTLi analyser (Siemens). We hypothesize that patients with chest pain can be diagnosed as accurate as standard of care (hs-cTnT and hs-cTnI) by using the VTLi POC assay. This study aims to define optimal cut-off concentrations for POC hs-cTnI at presentation to identify patients at low risk

and also at high risk of MI.

Study objective

Primary objective: To define the optimal cut-off concentrations for the POC hs-cTnI assay to rule out or rule in MI.
Secondary objective: To determine and validate an assay-specific 0/1-h algorithm for ruling out and ruling in MI.

Study design

Single-centre, prospective observational study.

All patients with suspected NSTE-ACS will undergo hs-cTn testing (T0, standard of care). Simultaneously, an additional capillary blood sample (fingerstick) will be drawn for POC hs-cTnI testing.
A second hs-cTn test may be performed as part of routine care (T1). This second test is intended to analyze whether there is a significant rise or fall in troponin to either rule-in or rule-out MI. The decision to perform the second cTn test is left at the discretion of the treating physician. Again, an additional capillary blood sample (fingerstick) will be drawn for POC hs-cTnI testing next to the second blood draw.
Patients will be monitored until discharge. There will be no post-discharge follow-up. Additional data relevant for this study will be extracted from the patient record database. Other demographic and clinical parameters at baseline will be taken into account.

Study burden and risks

In all patients, a fingerstick (POC hs-cTn) blood sample will be drawn at presentation at the emergency department (T0). If needed, after one hour (T1) a second fingerstick (POC hs-cTn) will be drawn. Besides the minimal risks of performing a POC finger prick test, no other risks are involved with study participation.

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

- Age >= 18 years
- Symptoms suggestive of MI and troponin measurement for ruling out/in ACS is indicated

Exclusion criteria

- Age < 18 years
- Pregnancy
- No 12-lead ECG performed or available
- Electrocardiographic ST-segment elevation
- Missing measurements of the POC hs-cTnI or standard of care hs-cTn
- Patients transferred from an outside hospital (e.g. for PCI treatment)
- An obvious non-cardiac cause for the chest complaints (trauma, pneumothorax, pneumonia, etc.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2024
Enrollment:	308
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	09-11-2023
Application type:	First submission
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	NL84129.100.23