Sample and method comparison with Minicare point-of-care device for cardiac troponin I assay at the emergency department.

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The primary objective is to compare the analytical performance (method and sample comparison) of Minicare high sensitive troponin I testing (POC, different sample types) and conventional venipuncture troponin I test in our central hospital…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48350

Source
ToetsingOnline

Brief title
Comparison of fingerstick versus venous sample for troponin I.

Condition

- Myocardial disorders

Synonym
acute coronary syndrome, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg

Source(s) of monetary or material Support: Afdeling Cardiologie te Viecuri Venlo,Minicare

Intervention

Keyword: Chest pain, Minicare, Point-of-care testing, Troponin

Outcome measures

Primary outcome

* Minicare POC (different sample types) vs conventional HS cTnI CL test (Method comparison)

* Minicare capillary vs. Minicare venipuncture and vs. Minicare plasma (Sample comparison)

The analyses linked to the primary objectives are:

* The agreement between POC (three sample types) and CL testing by using the Bland-Altman method.

* The relationship between POC (three sample types) and CL by linear regression and Pearson*s correlation.

* The agreement between different POC sample types by using the Bland-Altman method.

* The relationship between POC sample types by linear regression and Pearson*s correlation.

Secondary outcome

* To create an overview of baseline characteristics of the population.

* The mortality and major adverse cardiovascular events (MACE) of the population at 30 days. MACE is defined as a composite of cardiac death and

myocardial infarction.

* To compare final patients diagnosis (ACS vs. no ACS) and treatment based on POC venous troponin testing versus CL plasma troponin I testing versus HS cTnT plasma testing (regular patient care).

* To create an overview of the sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) of POC and standard laboratory troponin I testing.

* To determine amount of false positive and false negative results for the POC and if there is a significant difference compared to CL testing.

Study description

Background summary

Point-of-care (POC) troponin testing, defined as laboratory testing near a patient location with rapid availability of results, has attracted much interest in the emergency department setting (ED) and seems feasible. These devices might enable earlier decisions, reduce stay at the ED and improve patient flow. While an elevated troponin in patients with suspected acute coronary syndrome (ACS) confirms diagnosis and initiates adequate treatment, ruling out ACS aids in proper patient dismissal.
A next step could be ruling out myocardial infarction by the general practitioner (GP) or fast responder using an on-site POC troponin test. However, drawing venous blood might not be easily available to every GP, especially not during peak hours.
The Minicare cTnI is a bedside system which requires capillary blood, venous whole blood or plasma. The results of the troponin will be given within 10 minutes. It is a very sensitive troponin test, the most clinically sensitive available POC for c-Troponi.
Currently Minicare prepares for a high sensitive troponin analysis targeting a reliable result within an hour after onset of chest pain. The objective of this study is to determine if high sensitive troponin testing by Minicare has the same analytical performance as standard high sensitivity troponin I testing in our central hospital laboratory (ARCHITECT immunoassay analyzer, Abbott).

Study objective

The primary objective is to compare the analytical performance (method and sample comparison) of Minicare high sensitive troponin I testing (POC, different sample types) and conventional venipuncture troponin I test in our central hospital laboratory (CL) with the Abbott Architect.

Study design

This study is a prospective, observational, cohort study aiming to compare point-of-care high-senstive troponin I testing from different sample types with CL HS cTnI plasma samples.
All patients aged 18 years or older referred to the cardiac ED with chest pain suspected of ACS and having standard troponin tests ordered by their treating ED physician are eligible for the study. Written informed consent will be obtained from each study participant. STEMI patients who already underwent rescue PCI are eligible for the study as well.

Patients will receive standard medical care defined by their treating physician and based upon complaints, physical examination and laboratory results including standard HS cTnT analyses.
From every included patient capilary blood samples and an extra venous blood sample will be drawn to evaluate HS cTnI levels obtained with the POC instrument and CL. All samples will be collected twice, upon arrival in the ED (T=0) and one hour after arrival (T=1). This is in concordance with our regular HS cTnT protocol. In STEMI patients however the sample will only be drawn once.
The study will be conducted in a medium sized hospital with 24/7 PCI availability in the Netherlands. This cardiac ED has approximately 5500 presentations a year.
A registry of all included patients and their troponin results (POC, CL and HS cTnT) will be made to compare these testing methods. One study sample set per patient will be used for the method and sample comparison. The second study sample set will be used for evaluating the secondary objectives.
Study nurses and clinical chemistry analists will be trained on the study workflow including usage of the POC analyzer and adequate fingerstick technique with deep puncture of a suitable fingertip.

Study burden and risks

We expect no adverse events and there are no expected risks associated with this protocol. The burden on the patient is low. The fingerstick is a non-invasive procedure and for the collection of venous blood we use the regular troponin protocol at our hospital. The patients do not undergo an extra venipuncture.
We monitor patients for one month after their visit / admission by their medical file. There will be no additional visits.

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

* Patients 18 years or older with chest pain suspected of ACS.
* STEMI patient who already underwent rescue PCI; inclusion post PCI.

Exclusion criteria

* Out of hospital cardiac arrest.
* Patients with sudden onset tachycardia and a frequence 110 bpm or higher, (supraventricular or ventricular).
* Patients who are hemodynamically unstable or in which an acute non-coronary diagnosis is suspected, e.g. pulmonary embolism, thoracic aortic dissection etc.
* Patients already admitted for the same set of symptoms at a previous

healthcare institution before being transferred to the participating clinical site.
* Patients not willing or not able to provide informed consent due to their medical condition as judged by the physician

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2019
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-11-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	06-04-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL70186.096.19