Sample comparison with Siemens® point-of-care device for cardiac troponin I assay by using a heparin coated transfer device vs. non-heparin coated transfer device at the emergency department (validation study 2.0).

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

Summary

ID

NL-OMON49115

Source
ToetsingOnline

Brief title
Li-Hep vs. non-Li-Hep coated transfer device for POC HS cTnI.

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,Siemens

Intervention

Keyword: Heparin, Point-of-care, Siemens®, Troponin

Outcome measures

Primary outcome

Sample comparison:

The primary objective is to compare the analytical performance of Siemens® point-of-care high sensitive troponin I testing in different sample types by using the coefficient of variation. This comparison will comprise Siemens® POC capillary (2 fingersticks: one sample with a heparin coated transfer device and one sample with a non-heparin coated transfer device) vs. Siemens® POC venipuncture and vs. Siemens® POC plasma.

Secondary outcome

* The relationship between POC sample types by the Bland-Altman method.

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

* 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 determine the modified HEART score retrospectively based upon POC

capillary results in the population.

* To compare the retrospectively determined modified HEART score based upon POC capillary heparin coated transfer device with the retrospectively determined modified HEART score based upon POC capillary non-heparin coated transfer device.

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-Troponin. Currently Minicare prepares for a high sensitive troponin analysis targeting a reliable result within an hour after onset of chest pain.

In September 2019, the validation study 1.0 started, in which the cTnI result of the Siemens POC device on three sample types are compared. Interim analysis of the sample comparison was performed by regression analysis using Passing and Bablock, and calculating the Pearson correlation coefficient.
The Li-hep Plasma vs Li-hep venous blood show a very good correlation. For the capillary sample vs the Li-hep sample (both blood and plasma) the slope is 8-12% higher.
We hypothesize that the presence of the Li-heparin anti-coagulant in the venous draw lead to a slight reduction of the apparent cTnI concentration. By using a heparin coated transfer device for the capillary samples instead of an uncoated transfer device, this hypothesis will be tested.

Study objective

The objective of the study is to compare the analytical perfomance of POC Hs cTnI testing in different sample types. This will be achieved by taking:
* Two capillary samples: one sample with a heparin coated transfer device (drawn from a finger of the right hand) and the other one with a non-heparin coated transfer device. (drawn from a finger of the left hand)
* One extra venous blood sample: for POC venous and POC plasma analysis.
We hypothesize that three different sample types of Siemens® POC high sensitive troponin I (HS cTnI) show the same analytical performance when using a heparin coated transfer device instead of a non-heparin coated transfer device. The use of capillary blood as interchangeable sample type would enable on-site POC troponin testing.

Study design

This study is a prospective, observational, cohort study aiming to compare point-of-care high-sensitive troponin I testing from different sample types: venous Li-hep blood, Li-hep plasma, capillary sample without anticoagulant and capillary sample with Li-heparin.
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, including patients with a STEMI who already underwent rescue/emergency percutaneous coronary intervention (PCI). Patients with (supra)ventricular tachycardia, cardiac arrest and patients in which an acute non-cardiac diagnose is suspected, will be excluded. Written informed consent will be obtained from each study participant.
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 two capillary blood samples (one with a heparin coated transfer device and one with a non-heparin coated transfer device) and an extra venous blood sample will be drawn to evaluate HS cTnI levels obtained with the POC instrument. The capillary sample with the heparin coated transfer device will be drawn from the right hand. The capillary sample with the non-heparin coated transfer device will be drawn from the left hand. All samples will be collected once, at one time point with a maximum of 10 minutes in between. This will be done during regularly ordered blood work at the cardiac ED/coronary care unit (CCU). Patients will not undergo extra venipuncture for study purposes only.
A registry of all included patients and their POC troponin results will be made to compare these testing methods.
Study nurses and clinical chemistry analysts 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

* Age 18 years or older.
* Referred to cardiac ED with chest pain suspected of ACS; inclusion at arrival (T<=0) or one hour after arrival (T<=1).
* Subacute STEMI or NSTEMI patients who have an indication for coronary

angiography but do not need rescue/emergency PCI.
* STEMI patients who already underwent rescue PCI; inclusion post PCI.

Exclusion criteria

* Out of hospital cardiac arrest.
* Patients with sudden onset tachycardia and a frequency of 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 recently 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):	18-06-2020
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	12-02-2020
Application type:	First submission

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	NL72445.096.20