Implementation of prehospital high Sensitive troponin and risk Stratification- validation phase

Published: 23-03-2023
Last updated: 06-04-2024

validation Phase objective: Primary objective is to validate the high sensitive Troponin Quidel Triage True hsTnI. Secondary objective is to determine the applicability and repeatability. The focus will be on the ease of use, time spent performing...

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON53821

Source
ToetsingOnline

Brief title
IMPRESS-validation

Condition

- Heart failures

Synonym
Acute coronary syndroom, chest pain

Research involving
Human

Sponsors and support

Primary sponsor: Ambulancezorg Rotterdam-Rijnmond ARR
Source(s) of monetary or material Support: Ministerie van OC&W,Quidel

Intervention

Keyword: Emergency medical service, High sensitive Troponin, Prehospital, validation

Outcome measures

Primary outcome

Agreement of Troponin measurement between central laboratory and POCT device,

numerical and as part of the HEART score.

Secondary outcome

Secondary objective is the ease of use, time spent performing the test.

Study description

Background summary

Yearly 17.000 patients with acute chest pain are seen by the ambulance service Rotterdam-Rijnmond, of which approximately 13.500 are presented to the emergency department (ED). Only a minority of these patients has a serious condition such as an Acute Coronary Syndrome (ACS). In hospital, high-sensitivity cardiac troponin (hs-cTn) assays, with or without the use of a systematic risk score, have extensively improved the diagnosis in patients suspected of ACS (1,2).
Newly point-of-care (POC) devices for cTnT/I can substantially reduce the turnaround time for hs-cTn and can be applied earlier in the acute care chain (3).
Improved triage of acute chest pain patients by use of POC troponin and systematic risk stratification with a risk score (the HEART score) in the ambulance might lead to diminished referral to the ED and an increased number of patients that can be left at home or seen by their general practitioner (4-7).
This study will be a three phased study assessing the validity, feasibility and safety of an extended prehospital triage in patients with acute chest pain by use of a high sensitive POC troponin I, consisting of an analytical validation of the high sensitive POC troponin, a careful educational program for ambulance nurses and a before-after intervention study. This phase is the validation phase

Study objective

validation Phase objective:
Primary objective is to validate the high sensitive Troponin Quidel Triage True hsTnI. Secondary objective is to determine the applicability and repeatability. The focus will be on the ease of use, time spent performing the test.

Study design

This study will be a phased study, consisting of before, validation and implementation.

this phase : Analytical validation of the Quidel Triage True hsTnI, repeatability and ease of use.

Prospective inclusion of 300 patients prehospital

SPECIAL NOTE:
In order to make sure the study will be performed as careful and safe as possible, each phase has to be finished and completed before the study can proceed to the next phase.
After this phase an interim analysis will be performed to ensure that the Triage True point of care device meets the required validity and ease of use to be embedded in the workflow of patients with chest pain in the prehospital setting.

Intervention

Patients experiencing an episode of acute chest pain will call the emergency services for help. The dispatcher will send out a call to an ambulance crew. They will bring the Quidel high sensitive POC troponin I assay. If the patient meets all the requirements, inclusion will be started. The ambulance nurse starts by determining the history, EKG, age and risk factor score. During this time the driver of the ambulance prepares the Quidel troponine array. The troponine is done after the other scores are known to prevent bias. Troponine will be determined in every patient 18 years or older with chest pain suggestive of acute coronary syndrome. Testing for troponine is not required in patients with obvious cause of non-cardiac chest pain like traumatic injuries, stabwounds, pulmonary disease, esophageal reflux, panic attacks, or broken ribs or other. The HEART score divides patients in three categories, Low risk (0-3), intermediate risk (4-6), and high risk (7-10). Patients with low risk of developing MACE can be left at home. The ambulance nurse needs to give follow up advice. Depending on the situation this advice can consist of an appointment with the general practitioner or to call back when certain symptoms worsen or persevere. Patients with intermediate risk (4-6) need to be presented at a nearby emergency department for further evaluation. Patients with high risk

(7-10) should be transported to the nearest hospital capable of percutaneous coronary intervention and coronary angiography.

Study burden and risks

There are no extra burden or risks. blood collection through usual care IV and calculation of HEART-score.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria: >= 18 age with acute chest pain suggestive of cardiac

chest pain or acute coronary syndrome.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: ST-elevation on ECG, new left bundle branch block, systolic blood pressure below 90 mmHg, tachycardia above 140 beats per minute, clinical instability, signs of acute heart failure, terminal kidney failure, pregnancy, life expectancy of less than 3 months, obvious non cardiac cause of acute chest pain, inability to provide a written informed consent or inappropriate knowledge of English or Dutch language.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	300
Type:	Anticipated

Ethics review

Not approved

Date:	23-03-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL80818.078.22