H232: Analytical Validation of the Roche Cardiac Reader

Published: 14-04-2016
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Primary Objective: To assess the analytical performance of the cardiac reader Secondary Objective(s): To assess the user friendliness of the device (handling, analytical speed).

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

Summary

ID

NL-OMON43458

Source
ToetsingOnline

Brief title
Cardiac Reader Validation

Condition

- Myocardial disorders
- Embolism and thrombosis

Synonym
heart attack, Myocard infarction

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Apparaat ter beschikking gesteld door Roche;extra buisjes worden besteld door het laboratorium,Roche diagnostics

Intervention

Keyword: D-dimer, NT-proBNP, Point-of-Care, Troponin T

Outcome measures

Primary outcome

Main endpoint is the comparison with the reference method, and reproducibility

of measurements. For statistical criteria, see the corresponding section.

Secondary outcome

We will document the time needed to generate a result (pre-analyses as well as

measurement time) using the H232. Also, user friendliness will be assessed.

Study description

Background summary

D-dimer, troponin T and NT-proBNP are three laboratory tests that are frequently ordered in emergency situations (suspected thrombosis / pulmonary embolism, myocardial infarction, heart failure). The standard procedure in which tubes are sent to the laboratory for measurements are time-consuming, and might slow down decision making. The Roche cardiac reader H232 is a point-of-care device, which has the advantage that these parameters can be measured at the bedside of the patient. This saves time and can thus save health costs.

Study objective

Primary Objective: To assess the analytical performance of the cardiac reader
Secondary Objective(s): To assess the user friendliness of the device (handling, analytical speed).

Study design

We will assess the analytical performance of the roche cardiac reader. This includes 3 analytes: D-dimer, NT-pro-BNP and Troponin T. For each analyte we will need 50 samples in order to make a proper method comparison.
Blood for measurement of these analytes in our daily routine (roche cobas platform) is drawn in lithium heparine tubes (Greiner) with gel. Blood for

measurement on the H232 cardiac reader has to be drawn in a hepine tube without get. Therefore, we have to collect an additional tube for validation purposes.
The study is designed as follows:

- Each patient for whom one of the analytes of interest is ordered (d-dimer, NT-pro-BNP, troponin T) will be asked to donate extra blood:
o 1 lithium heparine tube (without gel) in case of NT-pro BNP or Troponin T
o 1 lithium heparine tube (without gel) and 1 sodium citrate tube in case of d-dimer.
- The material will be send to the lab, the standard tube (with gel) will be processed as usual (measurement of analyte on the Roche Cobas).
The materials will be centrifuged first to generate plasma.
- The lithium heparine tube without gel will be used for measurement on the H232 cardiac reader. For this measurement, 150ul of uncentrifuged blood is needed
- The sodium citrate tube (only in case of a d-dimer measurement) will be centrifuged to generate plasma. The plasma will be kept refrigerated until measurement on the Innovance platform.
- The patient details will be anonimised, only a lab number and a result for both methods will be recorded.
- For each analyte, a sample with a high and low test result, generated with the reference method, will be selected and measured 5 times in a row on the H232 (reproducibility measurement).
- The generated results will be analysed statistically.

Intervention

Drawing additional blood sample from existing vena puncture

Study burden and risks

There is a need for point of care testing, since it offers shorter turn around times and therefore faster decision making. With this study we hope to improve patient management in the near future. These benefits outweight the very small risks that are concerned with the small volume of extra blood collection for the individual patients.

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

Adults for whom a venapuncture is performed for analyses of D-dimer, NT-proBNP and/or Troponin T

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2016
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	NL56492.100.16