IVDR Performance Evaluation TROPT Sensitive and Intermediate Precision cobas h 232

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON49463

Source
ToetsingOnline

Brief title
Performance evaluation TROPT Sensitive en cobas h 232

Condition

- Coronary artery disorders

Synonym
heart infarction, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics GmbH
Source(s) of monetary or material Support: zie g2

Intervention

Keyword: cardiac troponin T

Outcome measures

Primary outcome

The primary goal in this study is to determine the limit of detection of TROPT Sensitive.

Secondary outcome

Beside the limit of detection (C95) further cut-points will be determined with the overall data of the method comparison to Elecsys TnThs by Probit analysis

The lot-to-lot variability will be determined with the pairs of values resulting from the parallel measurement of different TROPT Sensitive lots in the method comparison experiment

The comparability of heparin blood to EDTA blood will be determined with the pairs of values resulting from the parallel measurement of different TROPT Sensitive lots with these two sample materials in the method comparison experiment

The intermediate precision of TROPT Sensitive and of cobas h 232 will be tested

Study description

Background summary

The medical need of cardiac troponin T determination is well described and TROPT Sensitive is a well-established assay. The original performance evaluation of TROPT Sensitive was carried out from April to November 1996 at five study sites with two lots. At this time the definition of acute myocardial infarction and unstable angina pectoris was different to the current definition. Therefore, the intended scope of TROPT Sensitive as an aid in

diagnosis of myocardial infarction has to be validated with the current clinical setting using the current patient population applying the latest definition for the diagnoses and conducted with the specific users of the assay. All these have changed since 1996. Therefore, the assay has to be re-evaluated to fulfill the requirement for certification according to IVDR. The re-determination of the intermediate precision of TROPT Sensitive in a general ward will be used to determine the intermediate precision for the assays of the cobas h 232 system as well.

Study objective

The objective of this evaluation is to confirm the specifications for limit of detection, lot-to-lot variation and influence of the sample material (Li-heparin vs. EDTA blood) of TROPT Sensitive in comparison to Elecsys TnThs and for intermediate precision of the assay. Supportively, in all method comparisons CARDIAC POC Troponin T is measured.
Furthermore, demographic data and clinical performance figures of TROPT Sensitive will be evaluated in an explorative analysis which is done for information only.
In the reference range part of the study it shall be shown that all samples that are below the 99th percentile of the reference method Elecsys TnThs are found negative with TROPT Sensitive.
For cobas h 232 it shall be demonstrated that reliable results can be obtained by near patient users with basic skills in a general ward using Roche CARDIAC POC Troponin T, Roche CARDIAC proBNP+ and Roche CARDIAC D-Dimer.

Study design

Due to the observational study design no diagnosis will be made, no treatment will be initiated and no medical decision will be taken.
From patients with chest pain complaints that have consented to participate 20 ml additional blood is drawn into EDTA or LiHeparine tubes. These materials will be used to perform analytical and diagnostic validation of the troponin tests.

Study burden and risks

The only burden for all patients is an additional loss of 20 ml of blood. In some cases collected during a venipuncture for routine care, in other cases an additional venipuncture is necessary.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

New-onset typical chest pain and other symptoms suggestive of acute coronary syndromes

Exclusion criteria

Age <21 years
Self-declared pregnancy
Breast-feeding women
Relative or spouse of the investigator

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-07-2020
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2020
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	NL73090.100.20