Clinical Performance of Elecsys® Troponin T hs Gen 6 in Subjects with Symptoms of Acute Coronary Syndrome

Published: 29-11-2022
Last updated: 08-02-2025

To determine the clinical performance of Elecsys® Troponin Ths Gen 6 relative to the clinical diagnosis at different time points after patient admission (T0, T1, T2, T3, T6) using the previously determined universal or combined sex-specific cut-off...

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

Summary

ID

NL-OMON56428

Source
ToetsingOnline

Brief title
PERFORM-TSIX Study

Condition

- Coronary artery disorders

Synonym
acute coronoaire syndrome, myocardial infarction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: acute coronoary syndrome, clinical evaluation, troponin T

Outcome measures

Primary outcome

primary endpoint: Negative predictive value (NPV) of troponin Ths measured by

the 6th generation test at T3

Secondary outcome

clinical performance of troponin Ths gene 6 at other time points after admission

Performance of the troponin Ths gene 6 assay when the assay is used in the

rapid rule-out algorithm as described by the European Society of Cardiology

(ESC)

Study description

Background summary

The Elecsys® Troponin T hs generation 6 assay is an immunoassay utilizing the electrochemiluminescence »ECLIA« technology for the quantitative, highly sensitive in vitro measurement of human cardiac troponin T (hcTnT) in human serum and plasma. The test uses two monoclonal antibodies specifically directed against hcTnT. The Elecsys® Troponin T hs Gen 6 assay has improved analytical sensitivity compared to the previous assay generation, detecting both free troponin T and binary and ternary complexes of troponin.
This study is being conducted to obtain approval for use of Elecsys® Troponin Ths Gen 6 in clinical practice by the regulatory authorities, including the US FDA, for CE Marking (EU), by the NMPA (China) and by the PMDA (Japan).

Study objective

To determine the clinical performance of Elecsys® Troponin Ths Gen 6 relative to the clinical diagnosis at different time points after patient admission (T0, T1, T2, T3, T6) using the previously determined universal or combined sex-specific cut-off value (the 99th percentile URL of a healthy reference

population).

Study design

Prospective, non-interventional, single-arm, longitudinal cohort multicenter study enrolling patients with signs and symptoms of ACS

Study burden and risks

The burden is a maximum of 4 extra venipuntures during admission, a maximum of 5 x blood sampling (19 mL) and 2 x follow-up by telephone. The only risks of the study are the possible side effects of a venipuntures.

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

Signed Informed Consent
Age >=20 Years
Subjects demonstrating symptoms suggestive of acute coronary syndrome and/or myocardial ischemia, such as any of the following:
Chest pain, pressure, or a burning sensation across the precordium and epigastrium
Pain that radiates to neck, shoulder, jaw, back, upper abdomen, or either arm
Acute onset or worsening dyspnea
Nausea, vomiting, or indigestion
Lightheadedness or syncope
Diaphoresis
Generalized weakness or fatigue
Troponin or other cardiac marker determination planned as part of suspected ACS routine care
Asymptomatic subjects with atypical symptoms in whom myocardial infarction is being suspected

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-01-2023
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Elecsys Troponin Ths Gen 6
Registration:	No

Ethics review

Approved WMO Date:	29-11-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-07-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-10-2024
Application type:	Amendment
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	NL82227.000.22