

European performance evaluation study for the Philips Minicare cTn-I system

Submission date 04/02/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/03/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Heart disease is the largest single cause of death throughout the European Union. Many patients with heart attacks (myocardial infarction, or MI) come to hospital with chest pain. In order to determine if this chest pain is due to a heart attack or is due to some other cause such as a chest infection or muscular pain, tests are performed. The two most important types of tests are the electrocardiogram (ECG) and blood tests to see if there is any evidence of heart damage. The test which is now used to detect heart damage in the blood is the measurement of a molecule called cardiac cTnI. The Philips Minicare cTn-I test used on the handheld Minicare I-20 instrument, is an In vitro diagnostic test for measuring cardiac troponin I (cTnI) in blood samples designed to be used at the point-of-care (POC) by healthcare professionals as well as in the clinical laboratory. The European Performance Evaluation Study of Minicare cTn-I system is a performance evaluation designed to test whether the Minicare cTn-I is suitable for the measurement of cTn-I as to help diagnose acute MI (AMI) for patients presenting at the emergency department (ED) with suspicion of an acute heart condition. Based on the results of this study, the device will be placed on the EU market/ put into service in accordance with all applicable laws and regulations. The main aim of this study is to test the performance of the Minicare cTn-I test on the Philips Minicare I-20 device. Clinical performance evaluation will be based on clinical sensitivity and specificity for the diagnosis of AMI of the Minicare cTn-I test in Li-heparin whole blood and in Li-heparin plasma samples. This study involves evaluating the final product developed as described in <http://www.isrctn.com/ISRCTN99484822>.

Who can participate?

Adults (at least 18 years old) with symptoms suggestive of a AMI

What does the study involve?

Participants have blood samples taken on arrival to hospital, then 2-4 hours later and then 6-24 hours later if they are still in the hospital by this time.

What are the possible benefits and risks of participating?

There is no direct individual benefit for participants, other than helping developing a faster method to determine blood levels of troponin which enables a faster diagnosis of a possible myocardial infarction. This is important because a faster diagnosis will lead to quicker treatment

and ultimately reduced damage to the heart tissue. There are no anticipated risks for the subjects participating in the performance evaluation. A blood sample will be used as normally used in a routine hospital setting. Further the study is observational, so no diagnosis will be done with our device. Diagnosis of the subjects will remain to be based on the hospital standard of care.

Where is the study run from?

Hospitals in the EU – France, Germany, Netherlands and Austria

When is the study starting and how long is it expected to run for?

November 2014 to December 2015

Who is funding the study?

Philips Electronics Nederland B.V., Handheld Diagnostics (Netherlands)

Who is the main contact?

Mr Diederick Keizer

Contact information

Type(s)

Public

Contact name

Dr Diederick Keizer

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

European performance evaluation study for the Philips Minicare cTn-I system: an observational study

Study objectives

To evaluate the clinical performance of the Minicare cTn-I test on the Philips Minicare I-20 device. Clinical performance evaluation will be based on clinical sensitivity and specificity for the diagnosis of AMI of the Minicare cTn-I test in Li-heparin whole blood and in Li-heparin plasma samples.

This study involves evaluating the final product developed as described in <http://www.isrctn.com/ISRCTN99484822>

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Germany: Ethik-Kommission der FAU (Friedrich-Alexander Universitat Erlangen Nurnberg – Medizinische fakultat), 31/03/2015, ref: 381_14 Mz
2. France: Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé (CCTIRS), 15/04/2015, ref: CCTIRS N° 15.329
3. Netherlands: Medisch-Ethische Toetsingscommissie van het Catharina Ziekenhuis te Eindhoven, 27/03/2015, ref: AN204-0280 341/4.18 347/5.6 (354a)
4. Austria: Ethikkommission der Medizinischen Universitat Innsbruck, 02/10/2014, ref: M14-1447

Study design

Multi-center prospective non-randomized open surveillance study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Measuring cardiac cTn-I at the patient's bedside as an aid in the diagnosis of myocardial infarction (MI)

Interventions

Patients will have blood samples drawn in the ER (or CCU) at three different time points: when possible t=0 at presentation at ED of the hospital (defined as baseline sample), followed at 2 – 4 hours, and at 6 – 24 hours after first blood sample if the patient is still in the hospital at these time points. About 550 patients suspected of ACS will be enrolled. Enrollment will be stopped after positive adjudication of 50 patients with confirmed AMI, including the 6-24 blood sample.

Intervention Type

Device

Primary outcome measure

Current primary outcome measures as of 21/09/2017:

Sensitivity and specificity of Minicare cTnI in Li-Hep whole blood and Li-Hep plasma, calculated using the 99th percentile URL value of 43 ng/L, measured at 0h, 2-4h and 6-24h after presentation

Previous primary outcome measures:

From each enrolled patient, Li-heparin plasma and Li-heparin whole blood samples will be analyzed using the Minicare cTn-I System. In parallel, Li-heparin plasma sample will be tested using the hospital standard cTn assay (Elecsys Troponin T high sensitive Roche). Leftover of Li-heparin plasma will be stored for further analysis (aliquots at -80°C).

The final diagnosis of AMI will be based on adjudication by an external board of cardiologists. Only patients with at least one cTn result above the 99th perc. URL using the hospital standard cTn method will be adjudicated. All other patients will be assumed non-MI.

Secondary outcome measures

Current secondary outcome measures as of 21/09/2017:

The positive and negative predictive value of Minicare cTnI in Li-Hep whole blood and Li-Hep plasma, calculated using the 99th percentile URL value of 43 ng/L, measured at 0h, 2-4h and 6-24h after presentation

Previous secondary outcome measures:

1. To estimate the positive and negative predictive value of the Minicare cTn-I System
2. To evaluate the overall agreement between the Minicare cTn-I Test System and the hospital standard cTn assay
3. To evaluate agreement between Li-heparin plasma and Li-heparin whole blood

Primary and secondary outcomes are related to the same data collection set and will be evaluated after close of the study and during data analysis.

Overall study start date

01/11/2014

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. ≥ 18 years old
2. Patients presenting with symptoms suggestive of ACS, at ED or CCU
3. Patients presenting for the first time after onset of symptoms
4. Onset of last episode of symptoms suggestive of AMI <12 hrs prior to presentation to ER
5. Signed Informed Consent Form

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

550

Key exclusion criteria

1. Patients already admitted for the same set of symptoms at a previous healthcare institution before being transferred to the participating clinical site
2. Patients not willing or not able to provide informed consent due to their medical condition as judged by the physician

Date of first enrolment

01/04/2015

Date of final enrolment

30/11/2015

Locations**Countries of recruitment**

Austria

France

Germany

Netherlands

Study participating centre

Department of Emergency and Intensive Care, Nuremberg Hospital (Klinik für Notfall- und Internistische Intensivmedizin; Klinikum Nürnberg)

Prof. Ernst-Nathan-Str. 1

Nuremberg

Germany

90419

Study participating centre

Pitié-Salpêtrière Hospital (CHU Pitié-Salpêtrière)

47-83 Boulevard de l'Hôpital

Paris
France
75013

Study participating centre
University Medical Center Goettingen
Robert-Koch-Straße 40
Goettingen
Germany
37099

Study participating centre
University Hospital Heidelberg (Uniklinik Heidelberg)
Im Neuenheimer Feld 672
Heidelberg
Germany
69120

Study participating centre
Henri Mondor Hospital
51 Avenue du Maréchal de Lattre de Tassigny
Creteil
France
94010

Study participating centre
St. Antonius Hospital (St. Antonius Ziekenhuis)
Postbus 2500
Nieuwegein
Nieuwegein
Netherlands
3430 EM

Study participating centre
Universitätsklinik für Innere Medizin III – Kardiologie und Angiologie
Anichstrasse 35
Innsbruck
Austria
A-6020

Sponsor information

Organisation

Philips Electronics Nederland B.V., Handheld Diagnostics

Sponsor details

High Tech Campus 29
Eindhoven
Netherlands
5656AE

Sponsor type

Industry

Website

www.philips.com/magnotech

ROR

<https://ror.org/02p2bgp27>

Funder(s)

Funder type

Industry

Funder Name

Philips

Alternative Name(s)

Koninklijke Philips N.V., Royal Philips, Royal Philips N.V., Philips & Co

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Netherlands

Results and Publications

Publication and dissemination plan

The study was intended for providing the regulatory required clinical evidence for the CE marking of the device. Therefore the study results are published as part of the device Instructions for Use. Furthermore the trialists are planning to publish in a peer reviewed journal in Q3-Q4 2017.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The study was intended for providing the regulatory required clinical evidence for the CE marking of the device. Therefore the participant level data is part of the Technical File of the device, owned by Philips. The data is held within Philips Handheld Diagnostics.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/09/2017	08/02/2018	No	No
Results article		09/04/2018	08/03/2023	Yes	No