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

Submission date
04/02/2015

Recruitment status
No longer recruiting

Registration date
13/02/2015

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

Protocol serial number
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 Ia santé (CCTIRS), 15/04/2015, ref: CCTIRS N" 15.329
3. Netherlands: Medisch-Etische 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

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

Sponsor information

Organisation
Philips Electronics Nederland B.V., Handheld Diagnostics

ROR
https://ror.org/02p2bgp27

Funder(s)

Funder type

Industry

Funder Name
Philips

Alternative Name(s)
Royal Philips, Royal Philips N.V., Philips & Co, Philips International B.V., Firma Philips & Co, Philips Electronics N.V., Philips Company, Koninklijke Philips N.V., N.V. Philips' Gloeilampenfabrieken, Koninklijke Philips Electronics N.V.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Netherlands

Results and Publications

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?
Results article		09/04/2018	08/03/2023	Yes	No
Basic results		27/09/2017	08/02/2018	No	No