

Performance testing of the Minicare cTnI system in the Emergency Department

Submission date 10/12/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/11/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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) 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 Lab 2 Go project is a European Union funded Research and Development project involving hospitals in the European Union. The aim of this study is to determine the value of a method of measuring cardiac cTnI at the patient's bedside (point of care testing). Point-of-care cTnI testing has the potential to accelerate diagnosis and improve patient care. A blood sample can be taken and tested by the doctor, nurse or paramedic to provide cTnI measurement during clinical assessment, rather than having to wait for laboratory results. The study aims to assess the analytical and clinical performance compared to available lab based reference systems.

Who can participate?

Adults coming to hospitals with chest pains

What does the study involve?

Blood samples tested using the point of care device under assessment

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Hospitals in the EU – Austria, France, Germany, Netherlands (UK)

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

December 2014 to June 2016

Who is funding the study?
European Union

Who is the main contact?
Mr Henk Peels
Henk.peels@philips.com

Contact information

Type(s)
Public

Contact name
Mr Henk Peels

Contact details
High Tech Campus
HTC29P2.69
Eindhoven
Netherlands
5656AE
+31 (0)653559459
henk.peels@philips.com

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Demonstrating Minicare, a miniaturized biophotonics platform for fast and lab-equivalent Point-of-Care diagnostics

Acronym
Lab2Go

Study objectives
The goal of the Lab2Go project is to bring a (handheld) Point-of-Care test-device to the next level of maturity by demonstrating it in real user environments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Proportionate Review Sub-committee of the NRES Committee South East Coast - Surrey. Ref: 14/LO/2012

Study design

The Lab 2 Go project is a European Union funded multicentre Research and Development project (project nr. 621035) involving 6 hospitals in the European Union.

The project is a study on suspected MI patients to determine the value of a method of measuring cardiac cTnI at the patient's bedside (point of care testing). The study aims to assess the analytical and clinical performance compared to available lab based reference systems.

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

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

Interventions

Patient blood will be tested on the POC device and the result compared to local Troponin Lab test results. The study does not interfere with routine patient treatment and does not alter the routine diagnosis of the patients condition.

Intervention Type

Device

Primary outcome(s)

For individual patients, blood samples will be tested on the POC device from up to three time points (t=0, t=2-4 hours and t = 6-24 hours). Each result is a quantitative TnI measurement which can be compared to results generated by the local Lab equipment.

Key secondary outcome(s)

Users (nurses) will be observed and interviewed to gather user feedback on the use of the system.

Data regarding the hospital workflow for MI patients will be gathered to allow determining whether workflow efficiency can potentially be improved with the introduction of POC testing.

Completion date

30/06/2016

Eligibility

Key inclusion criteria

1. ≥ 18 years old
2. Patients presenting with symptoms suggestive of ACS, at ER or CCU
3. Patients presenting for the 1st time after onset of symptoms
4. Onset of last episode of symptoms suggestive of AMI <12 hrs prior to presentation
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 requiring emergency treatment (respiratory or cardiovascular support, arrhythmia control, coronary reperfusion)
3. Cognitive impairment or inability to understand study information
4. Unwilling or unable to provide written consent

Date of first enrolment

01/12/2014

Date of final enrolment

01/06/2016

Locations**Countries of recruitment**

United Kingdom

England

Austria

France

Germany

Netherlands

Study participating centre

St George's Healthcare NHS Trust

London

United Kingdom

SW17 0QT

Study participating centre

National Institute for Health Research Sheffield, Clinical Research Facility
Sheffield
United Kingdom
S10 2JF

Study participating centre

Stichting Catharina Ziekenhuis
Eindhoven
Netherlands

-

Study participating centre

Klinik für Notfall- und Internistische Intensivmedizin
Nurnberg
Germany

-

Study participating centre

Universitätsklinik für Innere Medizin III Klinisches Studienzentrum Kardiologie & Angiologie
Innsbruck
Austria

-

Study participating centre

CHU Pitié-Salpêtrière AP-HP et Université Pierre et Marie Curie
Paris
France

-

Sponsor information

Organisation

Philips Electronics Nederland, B.V. - HandHeld Diagnostics

ROR

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

Funder(s)

Funder type

Government

Funder Name

European Union funded multicentre Research and Development project (project nr. 621035)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes