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Performance testing of the Minicare cTnI system in the Emergency Department

Submission date
10/12/2014

Recruitment status
No longer recruiting

Registration date
02/01/2015

Overall study status
Completed

Last Edited
13/11/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Study website
http://www.lab2go.eu/

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Gather user feedback on the usability of the system in the ED

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Available on website

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 measure
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.

Secondary outcome measures

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.

Overall study start date
01/12/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
In total for all participating hospitals 300-350 patients for analytical performance testing and 600-700 patients for clinical performance testing.

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
Austria

England

France

Germany

Netherlands

United Kingdom

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

Sponsor details
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Sponsor type
Industry

Website
www.philips.com/minicare

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

Publication and dissemination plan
No publications are envisaged related to this study.

Intention to publish date

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