

# Performance testing of the Minicare cTnI system in the Emergency Department

<b>Submission date</b> 10/12/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/11/2017	<b>Condition category</b> 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  
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## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Henk Peels

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## Additional identifiers

## 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.  $\geq 18$  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

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**Study participating centre**  
**Klinik für Notfall- und Internistische Intensivmedizin**  
Nurnberg  
Germany

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**Study participating centre**  
**Universitätsklinik für Innere Medizin III Klinisches Studienzentrum Kardiologie & Angiologie**  
Innsbruck  
Austria

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**Study participating centre**  
**CHU Pitié-Salpêtrière AP-HP et Université Pierre et Marie Curie**  
Paris  
France

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## **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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes