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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON40913

Source
ToetsingOnline

Brief title
Demonstrating Minicare

Condition

- Myocardial disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
acute coronary syndrome, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: myocardial infarction, Point of care, Troponin I

Outcome measures

Primary outcome

In both work packages multiple outcome measures are defined. Please refer to

the respective parts of the protocol.

At the end of the study, the Minicare platform (hardware and software) and the

troponin I test are in their final form and can undergo the CE marking process.

Secondary outcome

See study protocol

Study description

Background summary

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. The two most important tests to determine if this chest pain is due to a heart attack are the electrocardiogram (ECG) and the measurement of cardiac troponin in blood.
The Lab 2 Go project is a European Union funded multicentre Research and Development project (project nr. 621035) involving 5 hospitals in the European Union, Philips Electronics Nederland B.V. * HandHeld Diagnostics and industrial partners (Conworx Technology GmbH, MicroSystems (UK) Limited and Scienion AG). Philips together with its industrial partners has developed a new point of care analyzer (Minicare), a first test to run on the analyzer (troponin I) and software that steers the anaylzer and connects the analyzer to the hospital data bases. In this study the analytical performance and usability od the new analysis platform in hopsitals is being tested and the system refined where

necessary.

Study objective

The project determines the value of a novel method of measuring cardiac cTnI at the patient*s bedside (point of care testing). The study aims to assess the analytical and clinical performance of a point of care troponin I test using an novel handheld analyzer (Minicare), compared to available lab based reference systems.
The scope of the study is to validate and improve the analyzer, the test cartridge and configuration and the software used. Furthermore work-flow and performance studies are done to evaluate optimal use of the test system in triage of chest pain patients.

Study design

The Lab2Go project defines 7 work packages of which work package 2 (WP2, Analytical Performance) and work package 3 (WP3 Usability Performance & Acceptance) are relevant to this protocol.
In WP2, the analytical charcteristics of the newly developed anlayzer and test cartridge for measurement of troponin I are established by laboaratory staff. The study is carried out in two cycles. The analytical performance of the current versions of the analyzer and test cartridge as well as the software are assessed in cycle one and modifications are made if necessary. In a second cycle, the improved performance of the analyzer/cartridge/software are confirmed.
In WP3, usability performance & acceptance of the newly developed anlayzer, test cartridge and software in the hand of the intended users are established. The study is carried uit in two cycles. The usability performance & acceptance of the current versions of the analyzer and test cartridge are assessed in cylcle one and modifications are made tot the analyzer, software and/or cartdige if necessary. In a second cycle, the improved performance is confirmed.
In both work packages blood samples from patients in the participating hospitals are used. Part of the plasmas is sent to the central lab (the Philips' lab on the High Tech Campus in Eindhoven). There troponin I conc. is measured with a single routine troponin I test system. All materials leaving a hopsital can not be traced back to an individual patient except by employees of the collecting hospital who can trace back the sample by linking the study number to a patient.

Study burden and risks

The maximal burden for an individual patient may be
-removal of extra blood (max 15 ml onf three ocasions) during a regular venipuncture and/or

-finger stick (max 3 times)
-answering a few questions before venipuntcture (99th percentil study) or
-answering a few questions on the phone during a 30 day follow up (chest pain patients).

The risk is almost neglectible and limited to side effects of a venipuncture (which the patient undergoes anyway).
There is no benefit for a participating patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who undergo work up for chest pain

Patients with elevated troponin concentration, e.g. after cardiac surgery

Exclusion criteria

none,
only foor the 99th percentile reference study, the following criteria are used (stated in 4.2.11)
* Personal history of AMI or other cardiac diseases.
* Subject with hypertension
* Subject with known diabetes at the time of the enrollment.
* Subject with known renal insufficiency at the time of the enrollment
* Cardioactive drugs
* Recreational drug use

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2015
Enrollment:	765
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50027.060.14