Minicare I-20 cTnI usability testing in the ambulance setting at Witte Kruis.

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The purpose of the study is to examine how the Minicare I-20 fits into the ambulance workflow. Relevant process data of the ambulance workflow was collected (stage 1) looking specifically into chest pain patients. This second stage will focus on...

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON42842

Source
ToetsingOnline

Brief title
Minicare I-20 cTnI usability testing in the ambulance setting

Condition

- Heart failures

Synonym
accute coronary syndrome, heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ambulance, cTnI, Minicare I-20, Usability

Outcome measures

Primary outcome

The usability and user acceptance will be measured by means of questionnaires and interviews [Appendix B] designed to extract usability information from the paramedics who have been using the Minicare I-20 system in the field. The following topics will be addressed:

* Ease of use of the analyzer

* The fit in EMS workflow

* Cartridge storage

* Analyzer storage

* Ease of device portability

* Usability of the case designs

Device performance

Analysis of analyzer log files and Patient result forms will allow to assess:

* Device performance (Non-Reportable rate, LOG file errors)

* Device performance in carry case

Analyzer/Cartridge storage cases.

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paramedics who have been using the Minicare I-20 system in the field. The

following topics will be addressed

* Usability of the case designs

* Fit in the ambulance

* Transport to patient

* Workflow improvement compared to no-case?

* Cartridge cooling

Acceptance criteria

* At least 5 patients tested by at least 10 paramedics.

* Questionnaires from at least 10 paramedics

Secondary outcome

N.A.

Study description

Background summary

The Minicare I-20 is designed to detect troponin-I levels within 10 minutes. Performed at the Point Of Care (POC) by paramedics or physicians, it provides an additional piece of diagnostic information that can positively impact the efficiency of patient treatment. In particular for patients where no clear ST-abnormalities show on the ECG but suspicious physiological symptoms are observed, determining the troponin level on site can be a powerful aid in the diagnosis of the condition of the patient. It will allow the attending healthcare professional to assess the best care center (normal hospital or hospital with PCI center) for the patient

Study objective

The purpose of the study is to examine how the Minicare I-20 fits into the ambulance workflow. Relevant process data of the ambulance workflow was

collected (stage 1) looking specifically into chest pain patients. This second stage will focus on performing cTnI tests in the ambulance workflow using the Philips Minicare I-20 system. The aim is to:
* Determine how the system can be integrated into the ambulance workflow.
* Measure the usability performance of the system under ambulance conditions (RH, temperature, sunlight, portability, storage, etc.).

Study design

The Usability tests focus on measuring usability performance by performing capillary (finger stick) sampling in the ambulance flow. Performing tests with patient samples in the ambulance flow will generate vital data on the performance and usability of the Minicare I-20 in this use environment.
The test will be performed in or near a (non-moving) ambulance, typically during the time the ambulance crew is *on scene* performing their routine care for the suspected ACS patient.

The study objectives are:
* Gather Analyzer performance data
o Performing a Minicare cTnI test in the available time window (between arriving at the patient and depart).
o Monitor success / failure rate.
* Gather usability performance data
o System usability under ambulance conditions: varying RH and temperature conditions, and varying lighting conditions
o Cartridge storage: at ambulance station and in the ambulance
o Cartridge disposal
o Analyzer usability: storage in ambulance, portability
o User acceptance
* Part of the usability study is to gather feasibility and usability feedback on prototypes of dedicated transport cases. The cases provide a means for cooled storage for the cartridges, possibly charging of the analyzer and potentially connectivity of the analyzer to the Ambulance IT. The cases also allow easy and safe transport of the analyzer to the patient.
* Quality assurance in the ambulance setting (performing weekly QC tests)

Study burden and risks

* The impact on the patient is limited to collecting one finger stick sample. The total time needed to prepare the system and collect a blood sample is less than 2 minutes
* Patients will be informed and give consent for inclusion in the study. They will be offered to reconsider their participation after they have received initial treatment.
* Patient information will be collected and anonymized before being made available to investigators other than the medical personnel involved with the

study.
* On occasion ambulance staff will be interviewed by an investigator to analyze usability acceptance.

Contacts

Public
Philips

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NL
Scientific
Philips

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18 years old or older
suspicion of acute heart failure

Exclusion criteria

younger than 18 years old
no suspicion for accute heart failure
non-consenting

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-12-2016
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-01-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59490.078.16