Photoplethysmography to detect circulatory arrest: A study in patients with induced cardiac arrest

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1) To study PPG signal characteristics in relation to circulatory arrest in patients with induced circulatory arrest. 2) To construct a PPG-based algorithm for detection of circulatory arrest based on induced circulatory arrest data in patients. 3)...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51869

Source
ToetsingOnline

Brief title
DETECT-1

Condition

- Other condition
- Heart failures

Synonym
Cardiac arrest

Health condition

hartstilstand

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Cardiac arrest, Early detection, Photoplethymography

Outcome measures

Primary outcome

Sensitivity and specificity of the developed algorithm for circulatory arrest detection

Secondary outcome

- Positive predictive value of the developed algorithm for circulatory arrest detection
- Negative predictive value of the developed algorithm for circulatory arrest detection
- PPG-derived signal characteristics during circulatory and non-circulatory arrest
- Sources of noise
- Sources of false positive alarms
- Patient satisfaction scores
- Complaints regarding the fit of the wristband
- Correlation and agreement of heart rate measurements
- Correlation and agreement of oxygen saturation measurements
- Correlation and agreement of blood pressure measurements

Study description

Background summary

Every week in the Netherlands, 300 victims suffer from out-of-hospital cardiac arrest (OHCA). Early recognition and help are of the utmost importance as survival chances decrease with 5-10% per minute delay to treatment. Over the past decade, deployment of lay rescuers initiating cardiopulmonary resuscitation prior to ambulance arrival has contributed to shortening of treatment delays and improvement in OHCA survival to up to 23%. Unfortunately, for cardiac arrest victims without a witness, the chance of survival is dismal. Automated cardiac arrest detection and activation of the emergency medical chain may help to further shorten treatment delays and provide early help for victims of unwitnessed cardiac arrest. In the DETECT project, we aim to develop a smartwatch/wristband that is able to automatically detect cardiac arrest and alert the emergency services. This project is supported by the Dutch Heart Foundation. We aim to use photoplethysmography (PPG) to detect circulatory arrest non-invasively. This is an optical technique with which blood volume changes can be measured on the skin. It is well-known for its use to measure oxygen saturation at the finger tip or to monitor heart rate using a sportwatch. The current submission concerns the DETECT-1 study. This is a first study to come to above-described solution for automated cardiac arrest detection. It is an observational study in patients with short-lasting induced circulatory arrest during which we collect additional data (PPG signals) using a wristband. We will study the collected PPG signals in relation to the presence and absence of circulatory arrest. Subsequently, this data will be used to construct a PPG-based algorithm for automate cardiac arrest detection and its performance will be evaluated. It is important to emphasize that the induced circulatory arrests are regularly performed during clinically-indicated procedures (defibrillation testing after implantable cardioverter defibrillator (ICD) implantation and rapid ventricular pacing during valve placement during transcatheter aortic valve implantation (TAVI)) and are by no means a study-related intervention. For further information, I refer to Chapter 1 of the study protocol ('Introduction and rationale').

Study objective

1) To study PPG signal characteristics in relation to circulatory arrest in patients with induced circulatory arrest.
2) To construct a PPG-based algorithm for detection of circulatory arrest based on induced circulatory arrest data in patients.
3) To study the performance (sensitivity and specificity) of the developed PPG-based algorithm for detection of circulatory arrest in patients with induced circulatory arrests.

Study design

The DETECT-1 is a Dutch prospective multicenter observational cohort study performed in a hospital setting.

Study burden and risks

Given the observational nature of this study and the non-invasive comfortable wristband used for PPG signal recording, the medical risk associated with study participation is negligible. For ICD/VT ablation patients, an arterial line will be inserted in the radial artery to measure blood pressure invasively during the procedure. Complications following radial artery cannulation include permanent ischemic damage (0.09%), temporary occlusion (20%), sepsis (0.13%), local infection (0.72%), pseudoaneurysm (0.09%), hematoma (14.4%), bleeding 0.53%. Generally temporary occlusion of the radial artery has no serious sequelae. Permanent occlusion appears to be rare (0.09%) (14). In the majority of studies on which these incidences are based, the arterial line was inserted for longer term invasive monitoring (e.g. during intensive care unit stay). It is expected that complication rates will be lower with planned insertion of an arterial line under optimal circumstances and only for monitoring during the procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet one of the following
criteria:
- Undergoing ventricular fibrillation induction during defibrillation testing after ICD
implantation
- Undergoing rapid ventricular pacing during TAVR procedure
- Undergoing ventricular tachycardia ablation
Additionally, a subject must meet all of the following criteria:
- Age => 18 years
- Fitting the wristband

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from
participation in this study:
- Unwilling or unable to provide informed consent
- Known hemodynamically relevant subclavian artery stenosis
- Medical issues that interfere with wearing of the wristband (e.g. skin disorders)
- Unavailability of wristband used for PPG recording

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-03-2022
Enrollment:	207
Type:	Actual

Medical products/devices used

Generic name:	CardioWatch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-12-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80256.091.22