Automated cardiac arrest detection using a smartwatch: A simulation study to DETECT sudden falls

Published: 30-03-2023
Last updated: 31-08-2024

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

Summary

ID

NL-OMON56025

Source
ToetsingOnline

Brief title
DETECT-2

Condition

- Other condition
- Heart failures

Synonym
fall detection

Health condition

Detectie van een val

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Accelerometer, Cardiac arrest, Fall detection

Outcome measures

Primary outcome

To construct an algorithm for detection of cardiac arrest related falls using wrist-derived accelerometer signals from simulated sudden falls and non-fall movements and study the sensitivity and specificity of the developed algorithm.

Secondary outcome

1. To study wrist-derived accelerometry signal characteristics in relation to sudden falls, soft falls and non-fall-motions in healthy subjects who simulate falls.

2. To study positive and negative predictive value of the algorithm for sudden falls.

3. To study sensitivity and false positives of an algorithm to detect soft falls.

4. To identify sources of noise interfering with correct accelerometry-based measurement of movements.

5. To study false positive rates of the recently developed first PPG-based cardiac arrest detection algorithm (DETECT-1) in this controlled study setting

6. To validate the steps per minute recorded by the CardioWatch by the steps per minute recorded by the CE/FDA certified Actigraph.

7. To validate the active calories per minute recorded by the CardioWatch by

the active calories per minute recorded by the CE/FDA certified Actigraph.

Study description

Background summary

While survival from out-of-hospital cardiac arrest has markedly improved over the past decade, for victims of unwitnessed cardiac arrest medical assistance often comes too late. Automated cardiac arrest detection and alarming would be an ideal solution to provide early help for this large subset. In the DETECT project, we aim to develop a smartwatch with the functionality of automated cardiac arrest detection and alarming. The primary sensor technology used to detect cardiac arrest is photoplethysmography (PPG). This is an easy-to-understand technology based on reflection of light to detect absence of pulsatile flow at the wrist. In the DETECT-1 study, a PPG-based algorithm for cardiac arrest detection is being developed using data from patients with short-lasting induced circulatory arrests. However, to come to a reliable cardiac arrest detection algorithm with low false positives, we need to take into account additional sensor data to confirm or exclude the presence of circulatory arrest. Accelerometer sensors measure acceleration and provide information on human movement. Since a first manifestation of cardiac arrest is sudden physical collapse without subsequent movement, these sensor data may provide valuable information to exclude or confirm cardiac arrest. For example, in case a patient continues to walk, this cannot be a cardiac arrest. In case, a patient collapses and shows no movement, a cardiac arrest is more likely.

Study objective

In the DETECT-2 study, we aim to construct an algorithm for detection of cardiac arrest related falls using wrist-derived accelerometer signals from simulated sudden falls and non-fall movements. The sensitivity and false positive rate of the developed algorithm for sudden fall detection will be studied. Additionally, collected data of the PPG sensor will be used to study false positive rates of the recently developed first PPG-based cardiac arrest detection algorithm (DETECT-1).

Study design

The DETECT-2 is a Dutch prospective simulation study performed in a controlled setting.

Study burden and risks

In this study, the participants will be asked to simulate falls. Risks associated with these falls could be bruises, abrasions and in the worst case more serious injuries, such as fractures. To minimize the risk of injuries, the study will be performed in a controlled setting on a soft surface and under supervision of trainer. Furthermore, the included subjects will be healthy to minimize the risk of injury as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged between 18 and 40

- Fitting the wristband

Exclusion criteria

- Unwilling or unable to provide informed consent
- Medical issues that interfere with wearing of the wristband (e.g., skin disorders)
- (Physically) unable or unwilling to perform the (fall-)motions
- Relevant health issues (e.g. osteoporosis)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-08-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	CardioWatch 287-2
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-03-2023
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2023
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	NL82171.091.23