Atrial Fibrillation Detection using Photoplethysmography at the Wrist

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The objectives of this study are to acquire PPG data in AF patients simultaneously with reference measurements (ECG) and to develop interpretation algorithms of PPG features to detect AF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON42452

Source
ToetsingOnline

Brief title
Atrial Fibrillation Detection

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation, Supraventricular Tachycardia

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Onderzoeksconsortium IMPULSE 2

Intervention

Keyword: Algorithm, Atrial Fibrillation, Photoplethysmography

Outcome measures

Primary outcome

The main study parameters are simultaneous ECG, PPG, and accelerometer

recordings that can be used to develop AF detection algorithms.

Secondary outcome

Not applicable.

Study description

Background summary

Atrial fibrillation (AF) is the most common cardiac arrhythmia. Heart rhythm monitoring in patients with AF is important for the following purposes: assessing treatment efficacy for rate or rhythm control, evaluating safety and efficacy of antiarrhythmic drug therapy and ablative procedures, finding the correlation between documented arrhythmias and symptoms, and monitoring AF burden to determine stroke risk. Moreover, there is a need for screening tools that can detect silent AF in the elderly population, as this will help preventing embolic stroke. The development of accurate detection of AF by devices is imminent and ambulatory monitoring devices that provide long-term monitoring capabilities, instant feedback, simplicity, every-day use, and a non-invasive nature, are needed. Philips Research has developed wearable technology based on photoplethysmography (PPG). This technology has the potential to provide the basis for an accurate long-term ambulatory monitoring device to detect AF that fits all the above stated criteria. The aim of this study is to explore whether this technology can indeed be used to detect AF.

Study objective

The objectives of this study are to acquire PPG data in AF patients simultaneously with reference measurements (ECG) and to develop interpretation algorithms of PPG features to detect AF.

Study design

The study is an observational study.

Study burden and risks

The study will consist of two phases. The first phase is based on a simple within-subject design. ECG and PPG data will be collected before (AF present) and after (AF not present) elective electrical cardioversion in the same patients. The second phase consists of a longer-term ECG and PPG (and accelerometer) recording during daily living.
In Phase 1, the only addition to usual clinical care is that patients will be wearing the ELAN wristband to collect PPG data and the Actiwave Cardio to collect ECG data for about 30 min before and after cardioversion. Phase 2 will be divided in two groups of patients. All will be patients who are undergoing Holter recordings as part of their usual clinical care. In group 2A, the ELAN wrist watch will be the only addition to usual clinical care. The second group will consist of patients waiting for an ablation procedure who will be invited to volunteer to undergo a short free-living simulation protocol at the start of the Holter recording. This is not part of their usual clinical care.
There are no risks associated with this study. Most of the study does not interfere with usual clinical care. The only addition will be the ELAN wristband (and the Actiwave Cardio). Only in the third group, patients will be asked to undergo a short (30-60 min) protocol of everyday activities, which is not part of usual clinical care. The burden for the patients is minimal in all cases.

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

In order to be eligible to participate in this study, a subject must have been diagnosed with Atrial Fibrillation and either be scheduled to have an elective electrical cardioversion (Phase 1), or be scheduled for a Holter recording (Phase 2). For Phase 2B patients are eligible when they are waiting for an ablation procedure.

Exclusion criteria

A potential subject will be excluded from participation in this study if he/she is not able to provide informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-10-2015
Enrollment:	60

Type:	Actual

Ethics review

Approved WMO Date:	17-08-2015
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	NL53827.100.15