

# RhythmCheck: validation of a PPG based smartphone application to detect atrial fibrillation.

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Aim: To determine the specificity and sensitivity of the AF app to detect AF.

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

## Summary

### ID

NL-OMON45415

### Source

ToetsingOnline

### Brief title

RhythmCheck

### Condition

- Cardiac arrhythmias

### Synonym

'atrial fibrillation', 'cardiac arrhythmias'

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Onze Lieve Vrouwe Gasthuis

**Source(s) of monetary or material Support:** OLVG Cardioresearch

## Intervention

**Keyword:** atrial fibrillation, diagnostics, smartphone application

## Outcome measures

### Primary outcome

The determination of sensitivity and specificity for detection of AF using a PPG based smartphone application.

### Secondary outcome

1. To determine the accuracy of the PPG based smartphone application to discriminate between other arrhythmias besides AF
2. Register external factors that effect the accuracy of the measurements.

## Study description

### Background summary

Atrial fibrillation (AF) is a cardiac arrhythmia characterised by continuous atrial activity and resulting in an irregular ventricular heart rhythm. It is the most common continuous arrhythmia and it affects more than 250.000 patients in the Netherlands. (Bots et al., 2015). The prevalence increases sharply with age and increases towards 7-10% in octogenarians. AF can be asymptomatic or result in irregular palpitations, dyspnoea or fatigue.

Depending of several risk factors complications of atrial fibrillation can occur, these include:

- Stroke due to dislodgement of a left atrial thrombus. (formation primarily in the left atrial appendage) In pacemaker patients it has been shown that even short episodes of AF (>6 minutes) are associated with an increased risk of stroke. (Benezet-Mazuecos, J et al., 2015) The risk of stroke can be significantly reduced by the use of oral anticoagulation. (Kirchhof, P et al., 2016)
- Heart failure can occur, especially when AF results in rapid ventricular contractions.

Early detection of AF is important in order to be able to initiate appropriate therapy to prevent stroke and heart failure. AF can be easily diagnosed using an electrical rhythm recording. New smartphone technology has introduced a new method to detect heart rhythm: photoplethysmographic (PPG) recording of the blood pulse in the finger (Gregoski, M. J., et al., 2012). PPG uses variation in reflection of light against tissue to measure the rhythm of blood perfusing the tissue. The AF-app is a novel software application for smartphone that uses PPG to detect cardiac arrhythmias including AF.

### **Study objective**

Aim: To determine the specificity and sensitivity of the AF app to detect AF.

### **Study design**

This is a prospective case-control study evaluating the AF app by comparing two non-invasive diagnostic methods. Patients with AF serve as their own control by taking measures before and after successful cardioversion.

### **Study burden and risks**

Patients will undergo standard electrocardiographic heart rhythm monitoring. As part of the study an additional smartphone based heart rhythm measurement will be performed. There are no risks related to this research.

## **Contacts**

### **Public**

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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 > 18 years with atrial fibrillation admitted for elective cardioversion for atrial fibrillation or who present with other intermittent arrhythmias

### Exclusion criteria

- Patients unwilling to participate
- Patients with >1% ventricular pacing by a pacemaker

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2018

Enrollment: 200

Type: Actual

## Medical products/devices used

Generic name: smartphone application  
Registration: No

## Ethics review

Approved WMO  
Date: 22-09-2017  
Application type: First submission  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO  
Date: 24-06-2019  
Application type: Amendment  
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	NL60442.100.17