

# Validation of a mobile bedside ECG Screening Tool for Arrhythmias in primary care practice

Published: 04-04-2017

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To validate the use of the Livv Mobiel ECG as a reliable office/bedside screening tool in primary care practice

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

## Summary

### ID

NL-OMON47469

### Source

ToetsingOnline

### Brief title

VESTA

### Condition

- Cardiac arrhythmias

### Synonym

atrial fibrillation

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W, Livv Mobile Health (Zwolle, Nederland)

## Intervention

**Keyword:** arrhythmias, ECG, mobile, smartphone

## Outcome measures

### Primary outcome

Specificity and sensitivity of Livv Mobiel ECG versus standard 12-lead ECG in detecting cardiac arrhythmias

### Secondary outcome

- 1) Agreement of the built-in software algorithm and cardiologist overread for atrial fibrillation
- 2) Nurse and/or primary care physician satisfaction regarding device utility

A sensitivity analysis will be performed in patients with symptoms ("symptom driven ECG") and in those in whom an ECG is performed as part of routine CVRM/diabetes care ("protocol-driven ECG").

## Study description

### Background summary

Patients frequently present to the family physician's office with symptoms as the result of a cardiac arrhythmia. These arrhythmias are frequently benign, such as incidental extra atrial or ventricular beats but may also include arrhythmias that warrant further work-up. Pulse examination and cardiac auscultation are directly available screening tools for a family physicians. When a cardiac arrhythmia is suspected, a 12-lead electrocardiogram (ECG) is performed. In addition to symptomatic patients, family physicians are also encouraged to do proactive case finding in patients who are at-risk for atrial fibrillation which is associated with a 5-fold increase in risk for stroke. Unfortunately obtaining a standard 12-lead ECG can be cumbersome, particularly during house visits, and is not available in every family practice. The use of a non-obtrusive smartphone-based single-lead ECG device ("Livv Mobiel ECG",

Livv Mobiel Health B.V., Zwolle, Netherlands) may lower this logistical threshold and may therefore improve gain in diagnostic screening. In symptomatic patients it may serve as immediate reassurance when an arrhythmia is not found during symptoms, while allowing direct action in case an arrhythmia is detected.

## **Study objective**

To validate the use of the Livv Mobiel ECG as a reliable office/bedside screening tool in primary care practice

## **Study design**

Patients who are subjected to undergo a standard 12-lead ECG at one of the participating family practices will be consented to the VESTA study. Study participants are asked to hold a small metal device for 30 seconds which remits the ECG signal to a dedicated data-secure smartphone. This recording will be stored and digitally sent to the investigators together with the standard 12-lead ECG for reference. The ECG recordings will be de-identified, shuffled and sent out to two cardiologists for independent review. The cardiologists record their findings in a secure electronic data capturing system (CastorEDC). In case of disagreement, a third cardiologist will be consulted by the investigators. Relevant medical information will be obtained from the electronic medical records from each participating center and entered in an online electronic data capturing system. At study completion, a short survey will be sent to all participating nurses and primary care physicians regarding device utility satisfaction.

## **Intervention**

A 30-second single-lead ECG registration by holding a small metal device that is connected to a secure smartphone ("Livv Mobiel ECG", Livv Mobile Health B.V., Zwolle, Netherlands). The investigational device is provided by the company.

## **Study burden and risks**

The nature of burden consists of holding a small metal ECG-signal detection device for 30 seconds. Although every possible effort is undertaken to guarantee patient safety, the risk of participation in this study (like any other study) may include a data "leak" of collected data.

## Contacts

### Public

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### Scientific

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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 who are scheduled for a standard 12-lead electrocardiogram in a primary care setting

### Exclusion criteria

Patients suspected of acute coronary syndrome, hemodynamically unstable, permanent pacemaker and/or ICD, unable to provide informed consent

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-04-2017

Enrollment: 250

Type: Actual

### Medical products/devices used

Generic name: Single-lead ECG registratie device

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 04-04-2017

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 24-05-2017

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 06-07-2017

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date:	18-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	16-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	26-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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	NL60281.018.16

## Study results

Date completed:	22-07-2018
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Actual enrolment: 214