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

Published: 04-04-2017
Last updated: 12-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	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 arrhyhmias 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

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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

Actual enrolment:	214