Mobile phones in cryptogenic strOke patients Bringing sIngle Lead ECGs to detect Atrial Fibrillation

Published: 11-04-2016
Last updated: 19-04-2024

The main objective of this study is to compare the incidence of detected AF in cryptogenic stroke patients by the AliveCor with the incidence of detected AF by a 7-Day Holter ECG.

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

Summary

ID

NL-OMON42745

Source
ToetsingOnline

Brief title
MOBILE-AF trial

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Cryptogenic stroke, Smartphone

Outcome measures

Primary outcome

The main endpoint will be the percentage of detected atrial fibrillation in

both the AliveCor group and the 7-Day Holter group after one year.

Secondary outcome

- Pro-BNP levels in all patients within 24 hours after cryptogenic stroke

- Percentages of atrial ectopy detected on the 7-day Holter monitor

- Left atrial diameter and volume

- Recurrent stroke

- Major bleeding

Study description

Background summary

A standard work-up of stroke patients to identify a cause of stroke consists of Computed Tomography (CT), CT angiography of head and neck arteries, transthoracic echocardiography, 12-lead 10-seconds electrocardiogram (ECG), blood tests and 24-hour ECG monitoring. A stroke is called *cryptogenic* if no cause can be determined after standard work-up. Current detection of atrial fibrillation (AF) after stroke is 2.0%. The detection of AF is extremely important because adequate detection and subsequent treatment can prevent recurrent stroke. Recent studies revealed that prolonged monitoring yields higher percentages of detected AF (12.0%). Devices used in these trials suffer from drawbacks. Our hypothesis is that a new, smartphone compatible device, producing a single lead ECG (AliveCor), can be used for prolonged ECG monitoring in cryptogenic stroke patients.

Study objective

The main objective of this study is to compare the incidence of detected AF in

cryptogenic stroke patients by the AliveCor with the incidence of detected AF by a 7-Day Holter ECG.

Study design

A multicenter randomized trial.

Intervention

After inclusion, patients will be randomized to either the AliveCor or a 7-Day Holter Monitor.

Study burden and risks

Both devices are battery powered and electrically safe. Patients face a 2-3% risk that AF is detected false-positively; this might lead to incorrect oral anticoagulation (OAC) prescription. However, a potential benefit of our stuy is that if AF is detected and treated with OAC, this significantly reduces the chance of recurrent stroke.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient with cryptogenic stroke
Patient with cryptogenic TIA

Exclusion criteria

- Known etiology of TIA or stroke
- Myocardial infarction <6 months before stroke
- Coronary Artery Bypass Grafting <6 months before stroke
- Severe valvular heart disease
- Documented history of atrial fibrillation or atrial flutter
- Permanent indication for oral anticoagulation at enrolment
- Patient has permanent OAC contraindication
- Patient is included in another randomized trial
- Left ventricular aneurysm on echocardiography
- Thrombus on echocardiographyRenal dysfunction (creatinine clearance <30 mL/min/1.73m2)
- Patient has life expectancy of <1 year
- Patient is not willing to sign the informed consent form
- Patient is <18 years of age
- Patient is considered a incapacitated adult
- Patient is not in possession of a smartphone with Android Operating System (OS) or iOS.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2016
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT02507986
CCMO	NL54103.058.15

Study results

Date completed: 09-11-2021

Actual enrolment: 57

Summary results

Trial is onging in other countries