Detection of paroxysmal atrial fibrillation using an automated Photo-plethysmography based artificial intelligence algorithm in ischemic stroke survivors

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23955

Source
NTR

Brief title
iStroke trial

Health condition

ischemic stroke

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: funding from Bayer

Intervention

Outcome measures

Primary outcome

To evaluate the accuracy and feasibility of a 30-day PPG based smartphone AF detection algorithm in cryptogenic stroke patients and compare it to the standard of care using a 3-day Holter measurement

Secondary outcome

The following parameters will be collected to complete data analysis.
- Demographic characteristics: age, sex, cardiovascular risk factors
- Baseline NIHSS-score
- Type of reperfusion therapy
- CHADSVASC score
- Stroke characteristics (e.g. stroke localisation, TIA or ischemic stroke)
- Diagnosis and duration of PAF
- The use of antiplatelets or anticoagulants

Study description

Background summary

Rationale
Among patients suffering from stroke or transient ischemic attack 19-33% is newly diagnosed or had a history of AF. In three randomized controlled trials, AF was found between 8 and 22 percent of patients with a cryptogenic stroke, using invasive or non-invasive monitoring. Early detection and adequate treatment of silent AF decreases the stroke risk in these patients. Appropriate screening of patients after stroke can be time consuming and difficult to arrange. Over the last years technology in wearables has improved which enables the patient to perform heart rhythm registrations in a non-clinical setting

Objective
The aim of this study is to evaluate the feasibility of PPG to detect episodes of atrial fibrillation in ischemic stroke survivors and compare it to usual care using a 3 day Holter monitoring.

Study Design
The study is a prospective cohort analysis.

Study population
The patients enrolled in this study are adults, above the age of 18 years, who are evaluated for a cardiac embolic source after having suffered a cryptogenic stroke.

Intervention
In addition to a standard 3-day Holter, stroke patients will be asked to perform an automated PPG measurement on their own smartphone two times a day, for 90 seconds for 30 days.

Main outcome measurement

To evaluate the accuracy and feasibility of a 30-day PPG based smartphone AF detection algorithm in cryptogenic stroke patients and compare it to the standard of care using a 3-day Holter measurement

Study objective

Our hypothesis is that the 30 day PPG based AF detection algorithm is at least equivalent to the 3 day Holter evaluation for the detection of paroxysmal atrial fibrillation

Study design

admission and 3 months

Intervention

Performing a PPG readout two times a day, during 90 seconds, with the own smartphone for 30 days.

Contacts

Public
OLVG
Femke Dessens

020 5108780
Scientific
OLVG
Femke Dessens

020 5108780

Eligibility criteria

Inclusion criteria

Adults, 18 years and above, cryptogenic stroke < 3 months evaluated for a possible cardiac embolic source and not previously diagnosed with atrial fibrillation at the time of inclusion. Cryptogenic stroke is defined as; 1) an ischemic stroke or transient ischemic attack (TIA) that is not lacunar, 2) absence of extracranial or intracranial atherosclerosis causing luminal stenosis, 3) no definite source of cardioembolism and 4) No other specific cause of stroke identified (e.g. arteritis, dissection, migraine/vasospasm, drug abuse)

Exclusion criteria

haemorrhagic stroke, lacunar infarction, known atrial fibrillation, other known cause of the ischemic stroke, inability to use a smartphone and language barrier.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8680
Other	ACWO OLVG : WO 19.097

Study results