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

Gepubliceerd: 20-05-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23955

Bron
NTR

Verkorte titel
iStroke trial

Aandoening

ischemic stroke

Ondersteuning

Primaire sponsor: Bayer
Overige ondersteuning: funding from Bayer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

admission and 3 months

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

OLVG
Femke Dessens

020 5108780

Wetenschappelijk

OLVG
Femke Dessens

020 5108780

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8680
Ander register	ACWO OLVG : WO 19.097

Resultaten