

Wavelet Wristband with Fibrichcek Algorithm for Atrial Fibrillation Detection

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Wavelet wristband with Fibrichcek algorithm is accurate to identify atrial fibrillation

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26823

Bron

Nationaal Trial Register

Verkorte titel

Wave-Convert

Aandoening

Atrial fibrillation

Ondersteuning

Primaire sponsor: Amsterdam UMC

Overige ondersteuning: Amiigo Inc. dba. Wavelet Health

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Determine the sensitivity and specificity of the Wavelet Wristband with Fibrichcek algorithm for detection for atrial fibrillation.

Toelichting onderzoek

Achtergrond van het onderzoek

Photoplethysmography (PPG) is frequently used as a method to detect heart rate in commercial wearable sensors based on detection of the pulse rate (being a surrogate for heart rate). The technology is based on small variations in light intensity either by transmission through tissue or reflection. Pulsed blood flow in an artery causes small wave variations that can be detected by the sensors and translated into an estimated heart rate. Photoplethysmography is currently being studied with regard to detection of rhythm disorders, like atrial fibrillation. Heart rate variability and advanced pulse wave form analysis can be used to make algorithms to detect atrial fibrillation.

In this study we will evaluate the accuracy of the Wavelet wristband with Fibrichck algorithm for detection of atrial fibrillation in patients in the setting of an electrical cardioversion.

Patients will wear the device for at least 5 minutes before and after the procedure. The wristband will record the pulse rate and the result be compared to a standard 12-lead ECG.

Doel van het onderzoek

Wavelet wristband with Fibrichck algorithm is accurate to identify atrial fibrillation

Onderzoeksopzet

Patients will have a pre-cardioversion PPG recording of 5 minutes done baseline and a 12 lead electrocardiogram will be performed during the recording. The cardioversion will take place and all patients will have a post-cardioversion PPG recording for 5 minutes and a 12 lead ECG. No follow up is required.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18 years
- Patients undergoing an elective electrical cardioversion
- Atrial fibrillation or atrial flutter/atrial tachycardia the day of the procedure.
- Willing and able to provide informed consent
- Willing and able to wear the wristband before and after the cardioversion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Urgent cardioversion
- Pregnancy
- Contraindication to anticoagulation

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	500

Type:

Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

Device data will be collected with due regard for the EU GDPR and recorded on electronic data collection forms on an iPad. The PPG recordings are stored on the Wavelet servers for subsequent analysis. The data will be stored with an anonymized 16 digit record ID. Separately, on the Amsterdam UMC servers, a dedicated and encrypted database will contain patient information, like patient number, age, sex, time of recording and ECG determined heart rhythm.

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	NL7761
Ander register	Amsterdam UMC : METC VUMC 2018.447

Resultaten