Wavelet Wristband with Fibricheck Algorithm for Atrial Fibrillation Detection

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26823

Source
Nationaal Trial Register

Brief title
Wave-Convert

Health condition

Atrial fibrillation

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Amiigo Inc. dba. Wavelet Health

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Determine the accuracy of the Wavelet wristband with Fibricheck algorithm to differentiate atrial flutter and atrial tachycardia from atrial fibrillation.

Study description

Background summary

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 Fibricheck 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.

Study objective

Wavelet wristband with Fribricheck algorithm is accurate to identify atrial fibrillation

Study design

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 minuts and a 12 lead ECG. No follow up is required.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

• Urgent cardioversion
• Pregnanacy
• Contraindication to anticoagulation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	500

Type: Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

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	NL7761
Other	Amsterdam UMC : METC VUMC 2018.447

Study results