Training and Validation of the Atrial Fibrillation Algorithm for Afi, a Novel Device for Arrythmia Diagnostics and Monitoring.

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To gather electrocardiogram, pulse oximeter and heart rate analog front-end, accelerometer and temperature data of patients undergoing electrical carioversion (ECV) for the treatment of AF, and to use the data for the training and validation of Afi...

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

Summary

ID

NL-OMON50909

Source
ToetsingOnline

Brief title
Algorithm for Afi

Condition

- Cardiac arrhythmias

Synonym
AF, Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Reinier de Graaf Groep

Intervention

Keyword: Atrial Fibrillation, Cardioversion, Electrocardiography, Monitoring

Outcome measures

Primary outcome

Validation of the algorithm will result in the calculation of four statistical

values. The sensitivity, specificity, F1-score and accuracy of the algorithm

will be determined. These values form the outcome of the study.

Secondary outcome

N.a.

Study description

Background summary

Atrial fibrillation (AF), the most common arrhythmia in Europa, requires better and earlier detection than currently possible. By earlier detection, severe consequences such as stroke and heart failure can be prevented. Afi, an experimental physiological parameter monitor, is capable of monitoring patients in a non-invasive manner and for a period of up to a month. In that way, even paroxysmal AF can be detected and treated in a very early stage.

Study objective

To gather electrocardiogram, pulse oximeter and heart rate analog front-end, accelerometer and temperature data of patients undergoing electrical carioversion (ECV) for the treatment of AF, and to use the data for the training and validation of Afi's AF detecting algorithm.

Study design

This research is a prospective, non-randomized, adjudicator-blinded observational study. Afi will perform measurements 60 minutes before and 60 minutes after ECV on patients undergoing ECV for the treatment of AF. During the ECV, Afi will be detached from the patient to prevent interference of the

device with the treatment. The collected data will be labeled after which part of the data will be used for training the algorithm (66%) and the remaining part will be used for the validation of the algorithm (33%).

Study burden and risks

This study is an observational trial which will be performed parallel to the conventional ECV care. Therefore, no extra burden or risks are expected to be associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

>= 18 years
Hospitalized for electrical cardioversion to treat atrial fibrillation
Prepared to use an experimental monitoring device
Willing and competent to give written informed consent

Exclusion criteria

Implanted pacemaker, defibrillator or assist device
Other heart rhythm than atrial fibrillation or sinus rhythm
Skin lesions or scars around the midsternal line of the thorax
Tattoos around the midsternal line of the thorax
Known allergy to one of the sticker components of the device
Participation in another clinical trial
Already participated in trial 'Algorithm for Afi'
Pregnancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2021
Enrollment:	165
Type:	Actual

Medical products/devices used

Generic name:	Afi
Registration:	No

Ethics review

Approved WMO Date:	21-05-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-04-2022
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
CCMO	NL76708.058.21

Study results

Date completed:	19-04-2023
Actual enrolment:	188