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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29538

Source
NTR

Brief title
Algorithm for Afi

Health condition

Atrial Fibrillation

Sponsors and support

Primary sponsor: Reinier de Graaf Gasthuis
Source(s) of monetary or material Support: Investigator Initiated

Intervention

Outcome measures

Primary outcome

Validation of AF detection algorithm

Secondary outcome

N/A

Study description

Background summary

Afi is a novel AF detection device that is designed to improve AF monitoring and lower health care costs. Afi will use four different sensors and an AF detection algorithm to annotate AF episodes as a guideline for the physician. For the development of Afi's algorithms, data must be gathered in a clinical setting for training and validation purposes. Patients who are hospitalized for electrical cardioversion (ECV) to treat AF will be monitored in two different health conditions within a single day: AF before ECV and sinus rhythm (SR) after ECV. This makes for a unique parallel comparison study population without the need for a long intensive follow-up.

Study objective

We hypothesize that our AF algorithm can detect AF events based upon the one-lead ECG data that Afi has collected with a sensitivity of 95% and a specificity of 80%.

Study design

Day of ECV, no follow-up

Intervention

Attaching Afi to the skin of the patient undergoing ECV, 60 minutes before ECV and 60 minutes after ECV

Contacts

Public
Reinier de Graaf Gasthuis
Jan Constandse

+31152603308
Scientific
Reinier de Graaf Gasthuis
Jan Constandse

+31152603308

Eligibility criteria

Inclusion criteria

≥ 18 years
Hospitalized for ECV to treat a priorly diagnosed AF
Prepared to use Afi
Willing and competent to give written IC

Exclusion criteria

Implanted pacemaker, defibrillator or assist device.
Other heart rhythms than AF or SR based upon conventional ECG
Skin lesions, scars, or tattoos around the midsternal line of the thorax
Known allergy to one of Afi’s or the sticker’s components
Participation in another clinical trial
Already participated in trial 'Algorithm for Afi'
Pregnancy

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:	Pending
Start date (anticipated):	21-06-2021

Enrollment:	166
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	28-05-2021
Application type:	First submission

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	NL9501
Other	METC Leiden Delft Den Haag : METC LDD P21.019

Study results

Summary results
N/A