Machine Learning and Artificial Intelligence for Early Detection of Stroke and Atrial Fibrillation

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- Enrolment of a representative cross-section of AF patients in Europe.- Detailed analysis of clinical and relevant parameters (digitalised ECG, cardiac imaging, blood biomarkers) that could be used during clinical practise for the diagnosis of...

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

Summary

ID

NL-OMON56279

Source
ToetsingOnline

Brief title
MAESTRIA-AFNET 10

Condition

- Cardiac arrhythmias

Synonym
atrial fibrilation

Research involving
Human

Sponsors and support

Primary sponsor: Kompetenznetz Vorhofflimmern e.V./Atrial Fibrillation NETwork (AFNET)
Source(s) of monetary or material Support: European Union's Horizon 2020 research and innovation programme under grant agreement No 965286.

Intervention

Keyword: artificial intelligence, Atrial Fibrillation, machine learning, Stroke

Outcome measures

Primary outcome

The general objectives of the MAESTRIA-AFNET 10 study on clinical epidemiology and medical management of atrial fibrillation (AF) are summarized as follows:

- Enrolment of a representative cross-section of AF patients in Europe.

- Detailed analysis of clinical and relevant parameters (digitalised ECG, cardiac imaging, blood biomarkers) that could be used during clinical practise for the diagnosis of atrial cardiomyopathy and patient*s outcome.

- The data sets will be assessed using Artificial Intelligence (AI) algorithms to characterise specific subgroups of AF or define novel outcome predictors.

Secondary outcome

Potential Outcome Parameters

* AA burden and vascular stiffness (measured by Preventicus Heartbeats and a wearable with photoplethysmographic -PPG- sensor to be coupled with a smartphone for continuous heart rhythm monitoring for 12 months).

* MoCA Cognitive function test.

* EQ-5D-5L Quality of Life questionnaire.

* Ischaemic events (systemic, myocardial and cerebral) at 12 months.

* Clinically relevant changes in CT/MRI for patients in which CT or MRI is clinically indicated.

- ECG analysis

- All variables from ECGs, CTs, MRIs & echos will be integrated for final

assessment.

Study description

Background summary

Atrial fibrillation (AF) and stroke are major health care problems in Europe. They are most often the clinical expression of atrial cardiomyopathy, which is under-recognised due to the lack of specific diagnostic tools.
Multidisciplinary research and stratified approaches are urgently needed to prevent, diagnose, and treat AF and stroke and preempt the AF-related threat to healthy ageing in Europe.
MAESTRIA is a European consortium of 18 clinicians, scientists and pharma industry partners who are at the forefront of research and medical care of AF and stroke patients funded by the EU Horizon 2020 programme (grant number 965286). The Atrial Fibrillation Network (AFNET) is one of the 18 partner institutions in this European consortium.
MAESTRIA will create multi-parametric digital tools based on a new generation of biomarkers that integrate artificial intelligence (AI) processing and big data from cutting edge imaging, electrocardiography and omics technologies. It will develop novel biomarkers, diagnostic tools and personalized therapies for atrial cardiomyopathy.
The MAESTRIA-AFNET 10 Study is an integral part of the MAESTRIA project. The study will collect relevant clinical parameters for AF from patients, this includes ECGs, cardiac CTs, MRIs and echocardiograms. Dedicated core labs will collect and homogenize the clinical data.
For atrial arrhythmias (AA) and vascular stiffness index (VSI) recording, patients will be provided with a measuring bracelet for continuous monitoring of heart rhythm with a photoplethysmographic (PPG) sensor coupled with a MAESTRIA_WP4 Study Protocol_final version 1.0_20220623 Page 10 of 52 smartphone app and the Preventicus Heartbeats® analytic service (Class IIa, CE marked), approved as consumer device. Preventicus is ISO 13485 certified.

Study objective

- Enrolment of a representative cross-section of AF patients in Europe.
- Detailed analysis of clinical and relevant parameters (digitalised ECG, cardiac imaging, blood biomarkers) that could be used during clinical practise for the diagnosis of atrial cardiomyopathy and patient outcome. The data sets will be assessed including but not limited to AI algorithms to characterize specific subgroups of AF or define novel outcome predictors.

Study design

International, multi-centre, non-interventional, observational registry. All patients will be treated in accordance to the current ESC AF Guidelines 2020.

Study burden and risks

As reported by patients such as side effects of the wearable

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

1. Patients with paroxysmal AF (clinically defined as AF episodes less than one week), or
patients with persistent AF (clinically defined as AF episodes longer than one

week),
or patients with permanent AF (no documented sinus rhythm or possibility to restore sinus rhythm by any means).
2. Patient (or legally acceptable representative if applicable) provides written Informed Consent to participate in the study. The patient has the option to give separate consent to donate extra volume of blood during routine blood collection, that can be used for biomedical research.
3. Patient is at least 18 years of age.
4. Patient must own a Smartphone with Apple iOS Version 14.5 (or higher) or with Android Version 8.0 (or higher).

Exclusion criteria

1. Any disease that limits life expectancy to less than 1 year.
2. All persons unable to provide informed consent.
3. All persons exempt from participation in a study or trial by law.
4. Any medical or psychiatric condition which, in the Investigator*s opinion, would preclude the participant from adhering to the protocol or completing the study per protocol.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2024
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	CardioWatch 287-1B
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-12-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	https://maestria-h2020.com/, https://www.ihuican.org.
CCMO	NL81963.068.23