RedStroke- Reducing Europe's stroke incidence: Highly cost-effective population screening programs for Atrial Fibrillation coupled with high diagnostic yield confirmation services.;Multicentre, international, investigator-initiated, controlled, randomised, double-blind clinical validation study of a smartphone application as screening tool for differentiation between sinus rhythm and atrial fibrillation

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To demonstrate that in patients with a CHA2DS2-VASc score of 2 or higher and no history of AF, the use of the Preventicus Heartbeats App increases the detection rate of AF compared to usual care and to demonstrate that AF screening with the app is...

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

Summary

ID

NL-OMON52879

Source
ToetsingOnline

Brief title
RedStroke

Condition

- Cardiac arrhythmias

Synonym
Artrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: University Hospital Basel (Switserland)
Source(s) of monetary or material Support: Europian Union Horizon 2020 SME Program,Horizon2020 centrale financieringsprogramma voor onderzoek en innovatie van de Europese Commissie,Preventicus

Intervention

Keyword: cost effectiveness, screening program Atrial fibrillation, Stroke

Outcome measures

Primary outcome

The primary endpoint of this study is the prevalence of AF confirmed by ECG in

the app group compared with the standard care group

Secondary outcome

The main secondary study outcomes are costs related to the AF screening with

the app and the compliance in each study group

Study description

Background summary

The Preventicus Heartbeats Application is a comprehensively clinically validated and CE marked medical device. It uses the smartphone LED light and camera to record a person*s pulse wave at the fingertip. Using proprietary algorithms, the pulse wave signals are then analysed and translated into an

ECG-comparable readout for clinical evaluation. Previous clinical studies demonstrated, that the Preventicus Heartbeats App reached an accuracy of 96% and a positive predictive value of 99% for detection of atrial fibrillation

Study objective

To demonstrate that in patients with a CHA2DS2-VASc score of 2 or higher and no history of AF, the use of the Preventicus Heartbeats App increases the detection rate of AF compared to usual care and to demonstrate that AF screening with the app is cost-effective

Study design

Multicentre, international, investigator-initiated, controlled, randomised, double-blind clinical validation study of a smartphone application as screening tool for differentiation between sinus rhythm and atrial fibrillation
AF screening with a smartphone application will be assessed in a double-blind randomised controlled trial. Patients will be randomly allocated in the intervention group *app* or control group *usual care*. All patients in both groups will receive the app and will be asked to perform a predefined measurement protocol. Investigators will be informed by Preventicus® if participants fail to provide the measurements according to the measurement protocol
App Measurement Protocol Study Time Duration 6 Months = 26 Weeks
App Use Weeks 1-2 Weeks 3-26
Frequency 2 x Day 2 x Week, on different days
Always in case of palpitations
Duration Approx. 1 minute each time
Procedure Place fingertip on the camera lens of the smartphone

Study burden and risks

Flashlight of the smartphone is active during measurement. This might cause some warmth release that might cause some skin irritation or pain at the finger tip

Contacts

Public
University Hospital Basel (Switserland)

Petersgraben 4
Basel CH-4031
CH

Scientific
University Hospital Basel (Switserland)

Petersgraben 4
Basel CH-4031
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

signed informed consent
• CHA2DS2-VASc score * 3, if patients less than 65 years old
• CHA2DS2-VASc score * 2, if patients 65 years or more

Exclusion criteria

• history of AF
• current anticoagulation treatment,
• cardiac implanted electronic device (ICD or/and PM)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Peventicus Heartbeats application (App)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-01-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	09-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	19-01-2024
Application type:	Amendment
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
ClinicalTrials.gov	NCT04108884
CCMO	NL72798.068.20