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The use of artificial intelligence and mobile health technologies to identify patients at the highest risk of atrial fibrillation (irregular and often abnormally fast heart rate)

Submission date
02/11/2021

Recruitment status
Suspended

Registration date
22/11/2021

Overall study status
Suspended

Last Edited
13/04/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is the most common heart rhythm disturbance (an irregular and often abnormally fast heart rate). Individuals with atrial fibrillation have an increased risk of developing strokes. AF can be persistent or paroxysmal (intermittent). People with AF can be unaware that they have the condition as they may not display any symptoms. If AF is identified earlier, strokes can be prevented with treatment in the form of a blood thinner (known as anticoagulation). In order to make a diagnosis, a heart tracing called an electrocardiogram (ECG) will be required.

Currently, over 100 individuals will need to be screened in order to pick one individual with AF. However, with our AF risk prediction machine learning algorithm, we predict that we can increase our yield in identifying patients at risk of developing atrial fibrillation. The AF risk prediction machine learning algorithm was developed from previous AF risk score models and primary care data. Early data has suggested that it reduces the number needed to screen to nine to pick one patient with atrial fibrillation.

There has been a recent surge in the number of technologies available for heart rhythm monitoring. As more people have smartphones, this provides us with more opportunities to monitor patients for longer and more frequently and ultimately, diagnose AF earlier. We would like to compare these technologies for AF detection among individuals identified as being at risk of atrial fibrillation by the AF risk prediction machine learning algorithm.

Aims:
1. To evaluate the potential benefit of using our machine learning algorithm to aid AF screening.
2. To compare the use of different health technologies for AF screening
3. To evaluate the optimal duration and frequency of rhythm monitoring for AF screening

Who can participate?
Participants who have been identified to be at risk of atrial fibrillation by the AF risk prediction machine learning algorithm. This algorithm will be run on general practice databases in the Hounslow primary care networks to generate a list of potential participants. They must not have a diagnosis of AF already and they must not have a cardiac electronic implantable device to be eligible to participate in the study.

What does the study involve?
The study involves screening the above participants for AF. All participants will have a single lead ECG using an AliveCor device with a Kardia App. If no AF is identified, the participants will undergo further monitoring for a period of 3 months. The participants will be divided into four groups by cluster randomisation of the general practices. The groups are as follows:
1. ECG group
This group will not have further monitoring after their single lead ECG.
2. Photoplethysmography group
This group will receive a Fibricheck App for their smartphones. They will need to take photoplethysmography recordings with their smartphone twice daily for 3 months. The recordings will be reviewed for the detection of atrial fibrillation.
3. AliveCor group
This group will receive an AliveCor device and a Kardia App for their smartphones. They will need to take single lead ECG recordings with their smartphone twice daily for 3 months. The recordings will be reviewed for the detection of atrial fibrillation.
4. Holter monitoring group
This group will receive 3 Holter monitors/ ECG patches over 3 months. The first monitor will be worn for 72 h. The subsequent monitors will be 24 h. There will be a 6-week interval between monitors.

If AF is identified at any point, the participant will be referred to their clinical team for appropriate treatment.

What are the possible benefits and risks of participating?
The possible benefits of participating are earlier identification of atrial fibrillation and earlier treatment for atrial fibrillation and therefore possible prevention of further AF related strokes or conditions. However, it is also possible there will be no direct benefit to the research participant. There are no foreseeable risks of participating in this study.

Where is the study run from?
West Middlesex University Hospital (UK)
Hounslow Clinical Commissioning Groups

When is the study starting and how long is it expected to run for?
May 2020 to June 2023

Who is funding the study?
Bristol Myers Squibb Pharmaceutical Limited (UK)
Chelsea and Westminster plus charity (UK)

Who is the main contact?
Dr Pavidra Sivanandarajah (Pavidra.sivanandarajah1@nhs.net)

Contact information

Type(s)
Scientific

Contact name
Dr Pavidra Sivanandarajah

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293493

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 293493, CPMS 50698

Study information

Scientific Title
Application of machine learning algorithm to identify patients at highest risk of atrial fibrillation for targeted screening

Acronym
AMLA-AF

Study objectives
Current hypothesis as of 29/11/2021:
The AF risk prediction machine learning algorithm can be used to identify patients at the highest risk of atrial fibrillation (AF) for targeted screening.

Previous hypothesis:
The PULsE AI machine learning algorithm can be used to identify patients at the highest risk of atrial fibrillation (AF) for targeted screening

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2021, London- Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester M1 3DZ, UK; +44 0207 104 8196; bloomsbury.rec@hra.nhs.uk), ref: 21/LO/0709

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Atrial fibrillation (AF)

Interventions
Current intervention as of 29/11/2021:
Participants will be identified using the AF risk prediction machine learning algorithm from the Hounslow primary care networks.
The study involves screening the above participants for AF. All participants will have a single lead ECG using an AliveCor device with a Kardia App. If no AF is identified, the participants will undergo further monitoring for a period of 3 months. The participants will be divided into four groups by cluster randomisation of the general practices. The groups are as follows:

1. ECG group
This group will not have further monitoring after their single lead ECG.

2. Photoplethysmography group
This group will receive a Fibricheck App for their smartphones. They will need to take photoplethysmography recordings with their smartphone twice daily for 3 months. The recordings will be reviewed for the detection of atrial fibrillation.

3. AliveCor group
This group will receive an AliveCor device and a Kardia App for their smartphones. They will need to take single lead ECG recordings with their smartphone twice daily for 3 months. The recordings will be reviewed for the detection of atrial fibrillation.

4. Holter monitoring group
This group will receive 3 Holter monitors/ ECG patches over 3 months. The first monitor will be worn for 72 h. The subsequent monitors will be 24 h. There will be a 6-week interval between monitors.

If AF is identified at any point, the participant will be referred to their clinical team for appropriate treatment.

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Previous intervention:
Participants will be identified using the PULsE AI machine learning algorithm from the Hounslow primary care networks.
The study involves screening the above participants for AF. All participants will have a single lead ECG using an AliveCor device with a Kardia App. If no AF is identified, the participants will undergo further monitoring for a period of 3 months. The participants will be divided into four groups by cluster randomisation of the general practices. The groups are as follows:

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If AF is identified at any point, the participant will be referred to their clinical team for appropriate treatment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Not applicable

Primary outcome measure
Detection of atrial fibrillation with a one-off ECG

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2020

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/11/2021:
1. Aged 18 years or above
2. Identified as high-risk for AF by our 'AF risk prediction machine learning algorithm
3. Access to smartphone depending on allocated screening group

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Previous inclusion criteria:
1. Aged 18 years old or above
2. Identified as high-risk for AF by our PULsE AI machine learning algorithm
3. Access to smartphone depending on allocated screening group

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,800

Key exclusion criteria
1. Have already a diagnosis of atrial fibrillation prior to study enrolment
2. Below the age of 18 years old
3. Presence of cardiac electronic implantable device

Date of first enrolment
11/04/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Middlesex University Hospital
Chelsea and Westminster NHS Foundation Trust
Twickenham Road
Isleworth
London
United Kingdom
TW7 6AF

Sponsor information

Organisation
Chelsea and Westminster Hospital NHS Foundation Trust

Sponsor details
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Chelsea Harbour
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United Kingdom
SW10 0XD
+44 (0)20 3315 6825
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Sponsor type
Hospital/treatment centre

Website
https://www.chelwest.nhs.uk/about-us/research-innovation-and-quality-improvement-riqi/research-development

ROR
https://ror.org/02gd18467

Funder(s)

Funder type
Industry

Funder Name
Bristol-Myers Squibb

Alternative Name(s)
Bristol-Myers Squibb Company, BMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Chelsea and Westminster plus charity

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Alivecor group version 1.1	25/10/2021	16/11/2021	No	Yes

Participant information sheet	ECG group version 1.0	26/10/2021	16/11/2021	No	Yes
Participant information sheet	Fibricheck group version 1.2	25/10/2021	16/11/2021	No	Yes
Participant information sheet	Holter group version 1.1	25/10/2021	16/11/2021	No	Yes
Protocol file	version 1.1	25/10/2021	16/11/2021	No	No
HRA research summary			28/06/2023	No	No