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Home blood pressure monitors in patients with atrial fibrillation

Submission date	Recruitment status	[ ] Prospectively registered
20/01/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/01/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/09/2021	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 08/08/2018:
Background and study aims
Atrial fibrillation (AF) is a common heart condition, affecting millions of people worldwide. The heart consists of two upper chambers (atria) and two lower chambers (ventricles). Inside the right atrium, a cluster of cells (sinus node) are responsible for firing electrical signals into the heart muscle causing the heart to beat regularly (sinus rhythm). When a person is suffering from AF, the normal signals from the sinus node do not work properly, causing other parts of the atria to fire chaotically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia). People suffering from AF have a much higher risk of developing other problems, such as stroke or heart failure. It is therefore very important to regularly monitor the heart rhythm and blood pressure of these patients in order to avoid future complications. Arrhythmias pose a major problem to the accurate measurement of blood pressure, and so the validity (correctness) of blood pressure measurements can be called into question. There is a wide range of blood pressure monitors available for use at home, although it is not known how accurate the measurements would be in AF sufferers. The aim of this study is to detect how well three home blood pressure monitors work at measuring blood pressure in patients with AF by comparing them with the gold standard (best known way of measuring blood pressure).

Who can participate?
Adults over 25 years old who have AF.

What does the study involve?
All participants attend two study visits at the study centre. Three different blood pressure monitors are tested separately against a mercury manometer (gold standard) in the same arm by two trained observers and a supervisor across a series of measurements following standard monitor validation procedures. The percentage that the test device measurements differ from the mercury standard by more than 5, 10 and 15mmHg (millimetres of mercury, which is the standard unit of measurement for blood pressure) are the collected.

What are the possible benefits and risks of participating?
Participants benefit from gaining a thorough understanding of their blood pressure level and how this varies (within a relatively short timeframe). There is a small risk of discomfort in the arm from the repetitive testing.

Where is the study run from?
NIHR/Wellcome Trust Birmingham Clinical Research Facility, Birmingham (UK)

When is the study starting and how long is it expected to run for?
December 2014 to June 2022 (updated 21/09/2021, previously: June 2020 (updated 17/08/2020, previously: May 2019))

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr James Hodgkinson

Previous plain English summary:
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Contact information

Type(s)
Scientific

Contact name
Dr James Hodgkinson

Contact details
Department of Primary Care & General Practice
Primary Care Clinical Sciences Building, Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 1214 148842
j.a.hodgkinson@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18905

Study information

Scientific Title
Validation of home blood pressure monitors in patients with atrial fibrillation

Study objectives
The aim of this study is to investigate whether home blood pressure monitors can be validated for use in patients with Atrial Fibrillation (AF).

Ethics approval required

Old ethics approval format

Ethics approval(s)
NRES Ethics Committee West Midlands - Solihull, 15/04/2015, ref: 15/WM/0081

Study design
Non-randomised diagnostic accuracy study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
All participants attend the NIHR/Wellcome Trust Birmingham Clinical Research Facility for two separate study visits. 3 different blood pressure monitors will be tested following standard monitor validation protocols over the 2 visits, with additional measurements undertaken for each monitor. The testing process will involve two trained observers and a supervisor using a standard mercury sphygmomanometer as a reference device with sequential same-arm comparison. Each set of monitor assessments (validation plus additional measurements) will take an hour, so total duration of the intervention will be three hours.

Intervention Type
Device

Primary outcome measure
Percentage of test device measurements differing from the mercury standard by more than 5, 10 and 15mmHg.

Secondary outcome measures
1. Average BP value over 1, 2, 3, 4, and 5 readings versus that for 6 readings for each individual
2. Variability of oscillometric devices compared to standard mercury technique

Overall study start date
01/12/2014

Completion date

30/06/2022

Eligibility

Key inclusion criteria
1. Initial diagnosis of atrial fibrillation, confirmed by 12 lead electrocardiogram and judged by primary care physician to be eligible to participate
2. Aged 25 years or over
3. Recruitment blood pressures should be in the range 90–180mmHg for SBP and 40–130mmHg for DBP. If patients with blood pressures outside these ranges are available they may be included but only to a maximum of four such pressures. The number of subjects in each recruitment range (SBP: low <130mmHg, medium 130160mmHg, high >160mmHg; DBP: low <80mmHg, medium 80100mmHg, high >100mmHg) must be between 10 and 12 subjects.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 33; UK Sample Size: 33

Key exclusion criteria
Three failed attempts in machine measurement.

Date of first enrolment
28/09/2015

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR/Wellcome Trust Birmingham Clinical Research Facility
Queen Elizabeth Hospital

Edgbaston
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham

Sponsor details
Institute of Cardiovascular Sciences
College of Medical and Dental Sciences
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

After the analysis on aggregate data is complete, publication will be sought in a peer reviewed scientific journal. Findings will also be presented at a national conference, SAPC and/or BHS, and on the dabl (http://www.dableducational.org) and BHS (http://bhsoc.org/bp-monitors/bp-monitors) websites. Where participating patients indicate that they would like to receive the results they will be sent a lay summary of the results with the opportunity to receive full details (published papers for example) if required.

Intention to publish date

30/06/2022

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No