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Remote monitoring of blood pressure in patients with high blood pressure during the COVID-19 pandemic

Submission date
24/02/2021

Recruitment status
No longer recruiting

Registration date
24/03/2021

Overall study status
Completed

Last Edited
12/02/2024

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Given the urgent need for effective monitoring and medical management of high blood pressure (hypertension) during the COVID-19 pandemic, this study will test the feasibility of remote medical management of hypertension utilizing personalised digital diary record assisted optimisation of blood pressure control.
This is a community-based trial with remote monitoring and medical management from the clinical team.

Who can participate?
Adults over 18 years, with poorly managed high blood pressure and access to a smartphone.

What does the study involve?
Participants will be assigned into two groups. Both groups will record blood pressure and COVID-19 symptoms into an electronic diary for 3 months. In addition, one group will be given a study medication called amlodipine with the aim to personalise the dosage to achieve optimal blood pressure management. Both groups will receive teleconsultations with the study doctor. The study will be delivered remotely for all participants.

What are the possible benefits and risks of participating?
Benefit of clinician access regarding blood pressure management during a pandemic, and participating in research. Little to no risk, study has been risk-assessed.

Where is the study run from?
Queen Mary University London (UK)

When is the study starting and how long is it expected to run for?
June 2020 to July 2021

Who is funding the study?
Innovate UK and Closed Loop Medicine Ltd.

Who is the main contact?
Dr David Collier, d.j.collier@qmul.ac.uk

Study website
https://www.qmul.ac.uk/whri/clinical-activities/william-harvey-clinical-research-centre-crc/patient-studies/personal-covid-bp/

Contact information

Type(s)
Scientific

Contact name
Dr David Collier

Contact details
Barts & The Royal London School of Medicine & Dentistry,
Queen Mary University of London
Charterhouse Square
London
United Kingdom
EC1M 6BQ
+44 (0)7961 383925
d.j.collier@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number
2020-002494-10

IRAS number
283209

ClinicalTrials.gov number
NCT04559074

Secondary identifying numbers
CPMS 47197, IRAS 283209

Study information

Scientific Title
Personalised electronic record supported optimisation when alone for patients with hypertension - a pilot study for remote medical management of hypertension during the COVID-19 pandemic

Study objectives

Participants' tolerability of side effects (as measured by VAS) will be related to their beliefs about the necessity of medication (necessity concerns), their concerns about side effects and their adherence to medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2020, London - Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), 20/HRA/2988

Study design
Interventional non randomized with observational sub study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details at https://www.qmul.ac.uk/whri/clinical-activities/william-harvey-clinical-research-centre-crc/patient-studies/personal-covid-bp/ to request a patient information sheet

Health condition(s) or problem(s) studied
High blood pressure

Interventions
This study for remote medical management of hypertension during the COVID-19 pandemic, utilizing personalized digital diary and open-label personalized dosing of amlodipine for optimization of blood pressure control in those participants with inadequate control of blood pressure. In this study, a participant's diary will be used to support home-based care for 1,000 patients with hypertension. A subset of 200 participants with uncontrolled hypertension will have an intervention with added low dose step-wise addition of amlodipine, delivered through remote oversight from healthcare professionals in the research study team. All the interactions with the study doctor and research study team do not require a clinic visit or meeting and will be carried out as a remote consultation every 2 weeks, or every 4 weeks in the observation group. Participants are asked to complete the digital diary, twice a day to record blood pressure, for a period of between 5 to 7 days, how much amlodipine (if any) was taken, and any effects of amlodipine experienced. Participants will also be asked to record any COVID symptoms in the diary.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
amlodipine

Primary outcome measure
Systolic blood pressure (mmHg/sphygmomanometer) at baseline and end of treatment in the intervention group

Secondary outcome measures
1. Blood pressure (mmHg) measured using sphygmomanometer daily SBP/DBP at baseline to end of treatment.
2. Tolerability of side effects of amlodipine measured using reports of side effects using digital diary at this will be assessed using daily diary completion data
3. Participant's beliefs about medicines measured using collection of data on participant's beliefs in the the Beliefs about medicines questionnaire, from baseline to end of treatment
4. Adherence to medicine measured using the questionnaires: Extence of Adherence, and the Making Medicines Work For You to medication at baseline to end of treatment
5. Quality of life measured using data from the questionnaire EQ5D. at baseline to end of treatment
6. SARS-CoV-2 COVID-19 symptoms and their timing measured using SARS-CoV-2 infection status as determined from health records. Rx (where possible) and BP from digital diary and baseline record

Overall study start date
01/06/2020

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Informed consent
3. Possession of a working smart phone that participant is able to independently use
4. Smartphone to support iOS versions 10.0 and newer or to support Android versions 5.0 (Lollipop) and newer
5. Smartphone to have minimum storage space required to install the digital diary: 250MB
6. Smartphone must have enough memory to run the digital diary
7. Either a) Participant account of a diagnosis of hypertension consistent with NICE/BIHS criteria on either 24h ABPM or repeated home measures of blood pressure, ideally prior to treatment Or b) Current treatment with antihypertensive medication

For the intervention study cohort
1. Sub-optimal blood pressure control defined as average systolic blood pressure of 140mmHg

or greater, and/or average diastolic blood pressure of 90mmHg or greater during the 5 days run-in period
2. Stable antihypertensive medication during assessment of eligibility

For the observational study cohort
1. Average systolic blood pressure of less than 140mmHg and/or average diastolic blood pressure of less than 90mmHg during the 5 days run-in period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1,000; UK Sample Size: 1,000

Key exclusion criteria
1. Current infection, or symptoms suggestive of SARS-2 COVID-19 at the time of screening (rescreening when recovered is allowed).
2. Known severe adverse reaction to amlodipine
3. Currently receiving >=10mg /day amlodipine
4. Participation in another clinical trial, where the participant has received IMP in the last three months, with the exception of the MRC Aim-Hy study (IRAS: 199550, REC: 16/EE/0294) where participants can be screened after 6 weeks from final visit
5. Pregnant or lactating or female of childbearing* potential not using adequate contraception (defined as oral contraceptive pill, IntraUterine Device, double barrier methods or abstinence as a clearly defined lifestyle choice)
6. Participants who have too limited or no understanding of spoken and/or written English in the opinion of the investigator
7. Participants who have hypersensitivity to dihydropyridine derivatives, amlodipine or to any of the excipients
8. Participants with obstruction of the outflow tract of the left ventricle (e.g. high grade aortic grade stenosis)
9. Participants with a known intolerance of fructose, sugar, glycerol, maltitol liquid (Liquid amlodipine is classed as sugar free, whereas the standard tablet contains lactose)
10. Co-morbidities incompatible with study participation e.g. that result in a participant being unable to complete daily entries satisfactorily via his/her smart phone
11. Participants lacking capacity
12. Unstable Heart failure (e.g. after myocardial infarction)

Date of first enrolment
26/10/2020

Date of final enrolment

30/05/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University of London
William Harvey Research Institute
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Barts Health NHS Trust
Whitechapel Road
London
United Kingdom
E1 1FR

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Barts Health - QMUL Joint Research Management Office (JRMO)
London
England
United Kingdom

E1 2EF
+44 (0)2078827275
research.governance@qmul.ac.uk

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Innovate UK; Grant Codes: 105319

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Closed Loop Medicine Ltd

Results and Publications

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

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. As per current protocol, dataset will be available for the The CI, PIs, study team, funders Closed Loop Medicine Ltd. and TMG members will have access to the final dataset from the eCRF for study analysis and reporting. The TSC will have access to interim data for safety analysis. All relevant data from this study will be submitted to peer review journals for publication following the termination of the study in line with sponsor and trust publication policy. The clinical study results will be accessible via EudraCT within one year of end of trial definition being met and Clinical trials.gov.

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			26/07/2023	No	No
Results article		07/02/2024	12/02/2024	Yes	No