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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
24/02/2021		Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/03/2021	Completed	[X] Results		
<b>Last Edited</b> 12/02/2024	Condition category Circulatory System	[] 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.

#### 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

#### Clinical Trials Information System (CTIS)

2020-002494-10

#### Integrated Research Application System (IRAS)

283209

#### ClinicalTrials.gov (NCT)

NCT04559074

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

- 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 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

#### 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 runin 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

# Study participating centre Oueen Mary University of London

William Harvey Research Institute Charterhouse Square London United Kingdom EC1M 6BQ

#### 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

#### **ROR**

https://ror.org/026zzn846

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Innovate UK; Grant Codes: 105319

#### Alternative Name(s)

UK Research and Innovation Innovate UK, innovateuk

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

#### **Funder Name**

Closed Loop Medicine Ltd

#### **Results and Publications**

#### 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?
Results article		07/02/2024	12/02/2024	Yes	No
HRA research summary			26/07/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes