# Telemonitoring of blood pressure in chronic kidney disease

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
23/08/2017		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
11/12/2017		[X] Results		
Last Edited	Condition category	Individual participant data		
12/08/2022	Urological and Genital Diseases			

### Plain English summary of protocol

Background and study aims

Blood pressure (BP) is believed to be an important risk factor among patients with chronic kidney disease (CKD). BP is associated with both risk of cardiovascular (heart) complications and progression of CKD. Studies of different BP targets are required to inform the treatment of the large number of people with CKD. BP is traditionally measured during hospital or general practice visits, but such visits are costly and possibly not representative of a patient's usual BP. Telemonitoring technology (where a patient measures their BP at home with a machine that automatically sends the results to a central computer where they can be reviewed by trained clinical staff) may help reduce the costs of accurately measuring BP, but its feasibility among people with CKD is uncertain. The aim of this study is to assess the acceptability of telemonitoring BP over 3 months.

Who can participate?

Patients aged 18 or over with chronic kidney disease

#### What does the study involve?

Participants are provided with a blood pressure machine and tablet device and trained how to use them. They are requested to measure their BP daily for the first month and then on alternate days for the next two months (so the total duration is 3 months). The blood pressure data is automatically sent from the BP machine to the tablet from where it is securely uploaded to the study database where it can be viewed by the research team. The acceptability and utility of telemonitoring are assessed.

#### What are the possible benefits and risks of participating?

The main burden of this study is the frequency of BP measurement (at least daily for 1 month and then alternate days for 2 months). However, the requirement for this would be explained clearly before starting and determining the acceptability of this is the main aim of this study. During months 2 and 3, participants' BP-lowering treatment may be changed. Such changes in treatment may be accompanied by side effects but these are rarely serious. Participants are advised of what to do should they become intrusive and they are encouraged to contact the research team if they wish to discuss them.

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? January 2016 to August 2017

Who is funding the study? British Heart Foundation (UK)

Who is the main contact?
Dr Richard Haynes
richard.haynes@ndph.ox.ac.uk

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Richard Haynes

#### Contact details

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# Additional identifiers

Protocol serial number OXHARP1

# Study information

#### Scientific Title

Telemonitoring of blood pressure in chronic kidney disease: a feasibility study (Oxford Heart and Renal Protection Study-I)

#### **Acronym**

OX HARP-I

#### Study objectives

The primary aim is to assess the participants' acceptability of telemonitoring BP over 3 months, assessed by the proportion of patients who provide at least 90% of the expected readings.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Oxford C Research Ethics Committee, 15/06/2016, ref: 16/SC/0274

## Study design

Non-randomized observational feasibility study

#### Primary study design

Observational

#### Study type(s)

Diagnostic

# Health condition(s) or problem(s) studied

Chronic kidney disease

#### **Interventions**

Willing and eligible patients will be provided with a blood pressure machine and tablet device and trained how to use them. They will be requested to measure their BP daily for the first month and then on alternate days for the next two months (so the total duration is 3 months). The blood pressure data is automatically sent from the BP machine to the tablet from where it is securely uploaded to the study database where it can be viewed by the research team. The acceptability of such methodology and its utility in clinical practice and future research are assessed.

#### Intervention Type

Device

## Primary outcome(s)

Proportion of participants who provide >90% of expected data points, assessed at 3 months

# Key secondary outcome(s))

- 1. Intra-individual variation in home BP, assessed at 1 and 3 months
- 2. Proportion of patients reaching target BP, assessed at 3 months

# Completion date

31/08/2017

# **Eligibility**

#### Key inclusion criteria

Men or women aged >=18 years at screening with either:

- 1. Estimated glomerular filtration rate (eGFR) >=20 <45 mL/min/1.73m2; OR
- 2. eGFR >=45 < 60 mL/min/1.73m2 and urine albumin:creatinine ratio >20 mg/mmol (or protein: creatinine ratio >30 mg/mmol)

# Participant type(s)

Patient

# Healthy volunteers allowed

#### Age group

Adult

# Lower age limit

18 years

#### Sex

All

#### Total final enrolment

25

#### Key exclusion criteria

- 1. Mean systolic BP <130 mmHg at screening visit
- 2. Planned change to BP lowering therapy during intensive monitoring phase
- 3. Acute vascular event (e.g. acute coronary syndrome, transient ischaemic attack or stroke) within last month
- 4. Medical history that might limit the patient's ability to comply with study procedures for the duration of the study

#### Date of first enrolment

01/11/2016

#### Date of final enrolment

15/04/2017

# Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre Oxford University Hospitals NHS Foundation Trust

Oxford United Kingdom OX3 7LE

# Sponsor information

#### Organisation

University of Oxford

#### **ROR**

https://ror.org/052gg0110

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

**British Heart Foundation** 

#### Alternative Name(s)

the bhf, The British Heart Foundation, BHF

#### **Funding Body Type**

Private sector organisation

#### Funding Body Subtype

Trusts, charities, foundations (both public and private)

#### Location

**United Kingdom** 

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator Dr Richard Haynes (richard.haynes@ndph.ox.ac.uk) according to the departmental data access policy (https://www.ndph.ox.ac.uk/about/data-access-policy).

## IPD sharing plan summary

Available on request

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/12/2018	12/06/2019	Yes	No
Basic results		13/09/2018	13/09/2018	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	23/11/2016	12/08/2022	No	No