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Telemonitoring of blood pressure in chronic kidney disease

Submission date
23/08/2017

Recruitment status
No longer recruiting

Registration date
11/12/2017

Overall study status
Completed

Last Edited
12/08/2022

Condition category
Urological and Genital Diseases

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Diagnostic

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

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

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

Overall study start date
30/01/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

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

England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
University of Oxford

Sponsor details
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

Sponsor type
University/education

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

Publication and dissemination plan
The trialists plan to publish in a peer-reviewed medical journal within one year of the end of the study. The protocol will be available at the time of publication.

Intention to publish date
31/12/2018

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?
Basic results		13/09/2018	13/09/2018	No	No
Results article	results	21/12/2018	12/06/2019	Yes	No
Protocol file	version 2.0	23/11/2016	12/08/2022	No	No
HRA research summary			28/06/2023	No	No