ISRCTN80586284 https://doi.org/10.1186/ISRCTN80586284

Screening for high blood pressure in the inpatient environment: the SHINE study

Submission date
20/08/2019

Recruitment status
No longer recruiting

Registration date
18/11/2019

Overall study status
Ongoing

Last Edited
23/05/2023

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
High blood pressure (also known as hypertension) is when the pressure of blood flowing through arteries in the body is higher than it should be. This makes the heart work harder to pump blood through the vessels around the body. High blood pressure is very common, with 1 in 4 people in the UK affected. If not treated, it can cause serious long-term health problems. Blood pressure is measured using a device called a blood pressure cuff or monitor. This measures how hard the heart is pumping blood through one of the arteries in the arm. The measurement can be performed in hospital, at the GP surgery or at home.

Previous research has told us that when people are in hospital, in pain or unwell, their blood pressure goes up, but we don't know by how much. Because of this, we don't know the correct level at which blood pressure should be considered either normal or high in hospital. This study will help answer this question.

Who can participate?
The SHINE study will recruit 200 people who are admitted to the John Radcliffe Hospital in Oxford.

What does the study involve?
Patients will be approached during their hospital stay and asked if they are willing to wear a blood pressure monitor for 24 hours after they have gone home. We will ask them to carry out their normal daily activities whilst wearing the monitor. We will then compare their blood pressure measurements in hospital to their blood pressure measurements at home. Using this information, we will then be able to define the blood pressure threshold in hospital which should be considered as 'elevated' or 'high'.

What are the possible benefits and risks of participating?
Benefits: It is possible that during the course of this study we will detect people with have high blood pressure that needs treatment. If so, we will contact the participant and their General Practitioner to recommend an appointment together to discuss this. Untreated high blood pressure can have long term effects on health. Picking it up as part of the study might benefit a person's health. Some people who take part in this study will not have high blood pressure and

therefore may not directly benefit from taking part in this study.
Risks: Blood pressure monitoring is a simple and common medical test. Because of this, we do not expect any serious risks to occur from participation. Some people find having their blood pressure taken uncomfortable. Completing the baseline and follow-up questionnaires will each take 15 minutes of a person's time.

Where is the study run from?
John Radcliffe Hospital, Oxford, UK

When is the study starting and how long is it expected to run for?
September 2019 to March 2033

Who is funding the study?
National Institute for Health Research Oxford Biomedical Research Centre

Who is the main contact?
Prof Peter Watkinson
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.7

Study information

Scientific Title
Screening for Hypertension in the INpatient ENvironment (SHINE): a prospective study of diagnostic accuracy among adult hospital patients

Acronym
SHINE

Study objectives
Presently, elevated blood pressure measurements among hospital inpatients are frequently dismissed. This may be owing to clinicians attributing such measurements to anxiety, pain or white coat hypertension. However, evidence suggests that patients with elevated blood pressure recordings in hospital frequently remain hypertensive in the community.

Untreated hypertension is associated with a progressive increase in blood pressure that can become treatment resistant. Therefore, hospital detection and timely management of hypertension offer an important opportunity to intervene and address this major cause of morbidity and mortality.

The overall aim of this study is to determine the optimal in-hospital blood pressure threshold(s) (index test) above which patients should receive post-discharge ambulatory blood pressure monitoring in the community (gold standard test), to detect the presence of undiagnosed hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2019, NHS Health Research Authority South Central – Oxford B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; 02071048046; nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0026

Approved 16/07/2020, HRA Confidentiality Advisory Group (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 797 22557; cag@hra.nhs.uk), ref: 20/CAG/0054

Study design
Prospective cohort diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
The identification of potential participants whose blood pressure exceeds the index test threshold will be automated using live, computerised algorithms. Patients identified as potentially eligible by the computerised algorithm will be approached during their hospital stay by a member of the clinical research team. If a patient expresses interest and provides consent for access to their medical records, they will undergo screening against the inclusion and exclusion criteria through questionnaires and review of their medical record. Eligible patients will be provided with information about the study before informed consent for participation is sought.

All consenting participants will receive ambulatory blood pressure monitoring at 8 weeks (+/-4) following discharge from hospital. This will be performed using a validated and automated Mobil-O-Graph ambulatory blood pressure monitor (IEM GmbH, Stolberg, Germany), calibrated to manufacturer standards. The monitor will be programmed to measure blood pressure twice per hour during daytime hours (07:00 to 22:00), and once per hour during the night (22:00 to 07:00) for a period of 24 hours. A minimum of 70% of the day time and 70% of the night time ABPM recordings must be successful in order to calculate the mean blood pressure for night and day and for the participant data to be analysed. Where less than 70% of the recordings in any category are successful, the participant will be asked to wear the monitor for a further 24-hour period in order to collect adequate data.

Intervention Type
Other

Primary outcome(s)
Determine the optimal in-hospital blood pressure threshold(s) (index test) above which patients should receive post-discharge ambulatory blood pressure monitoring in the community (gold standard test), to detect the presence of undiagnosed hypertension, using the following data:
a. Percentage of patients in the eligible hospital population who have a mean in-hospital blood pressure above the eligibility threshold and a series of ordinal blood pressure thresholds.
b. True positive, false positive, true negative and false negative classifications of hypertension at each of the index and ordinal thresholds, defined by ABPM as the gold standard test.
c. Sensitivity and specificity of the index threshold and each ordinal blood pressure threshold as a diagnostic predictor for the presence of hypertension.

Key secondary outcome(s))

1. Test the feasibility of utilising blood pressures recorded electronically during routine practice to identify patients with a mean blood pressure which exceeds the pressure thresholds defined in the study protocol. Performance and boundaries of the algorithm will be tested against validation scenarios to ensure correct performance before study commencement.
2. Develop an effective clinical pathway to follow patients from hospital to community, integrating individual hospital patient data with primary care health records and preventing duplication of investigations between primary and secondary care. The clinical pathway will be assessed using data collected from primary care practitioner and patient surveys to include:
2.1 Feedback regarding communication streams and integration of data with primary care health records
2.2 Percentage of eligible patients who comply with the protocol to complete community ABPM and arrange follow up with their primary care provider
3. Test the feasibility and acceptability of following these patients up in the community to conduct ABPM as a gold standard test for the diagnosis of hypertension. The feasibility and acceptability of the follow-up procedures will be assessed using data collected from primary care practitioner and patient surveys to include:
3.1 Percentage of eligible patients who comply with the protocol to complete community ABPM and arrange follow up with their primary care provider
3.2 Acceptability of ABPM and follow up procedures used in this study
4. Identify a device that will monitor and record the ambulatory blood pressure of these patients following discharge from hospital. Suitability and performance of the device will be assessed based on the percentage successful recordings made by the ABPM per patient and per cohort and percentage participant adherence with 24-hour wear of the ABPM.
5. Identify patient factors which are associated with diagnostic accuracy. Subgroup analysis will be performed according to baseline demographics and clinical status of participants
6. Establish the feasibility of delivery and cost of this service intervention for the service provider. We will report on the costs included in this study which would translate to clinical care, including costs of equipment, health care practitioner time to fit ABPM, patient communication items utilised to integrate routine hospital data with primary care records.

7. Follow up data will be collected for each patient at the following time points:
7.1 4-12 weeks post recruitment: 24 hour ambulatory blood pressure monitoring will be conducted
7.2 13 weeks: Contact participant to ask them to complete log of any subsequent consultation with their General Practitioner
7.3 13-26 weeks: completion of study feedback by participant and GP
7.4 52 weeks: Electronic data capture system access will be locked. At the end of the study all data retrieved for study analysis
7.5 10 years: Obtain data from the ONS and Hospital Episode Statistics Database

Completion date
01/03/2033

Eligibility

Key inclusion criteria
1. Willing and able to give written informed consent for participation in the study
2. Aged ≥18 years < 80 years
3. Admitted to hospital for an acute or elective medical or surgical condition
4. Pending discharge to a fixed abode within Oxford City
5. At least three in-hospital blood pressure recordings over a minimum of 24 hours for the index

admission
6. At least one blood pressure measurement during the index admission being recorded during night time hours (00:00 to 06:00) and one recorded during day time hours (10:00 and 20:00)
7. Identified by the BP algorithm at any 24-hour interval during that index admission, to have a running mean blood pressure which meets the eligibility thresholds, which are defined as: mean systolic blood pressure ≥ 120 mmHg
8. Registered with a General Practitioner and consents to his or her general practitioner to be notified of participation in the study and of results of investigations as part of this study
9. Able to comply with the study protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pre-existing diagnosis of hypertension or attending hospital with acute end-organ damage related to severe, undiagnosed hypertension including but not limited to: posterior reversible encephalopathy syndrome, hypertensive encephalopathy, ocular haemorrhage, hypertensive retinopathy, heart failure, acute vascular injury, stroke, myocardial infarction or angina
2. Pregnant, within three months post-partum or planning pregnancy during the course of the study
3. Receiving or requiring treatments which might be used for the management of hypertension, for reasons other than this, e.g. beta-blockers for migraine, angiotensin-converting-enzyme inhibitors for renal disease or aldosterone antagonists for the treatment of ascites
4. Diagnosed with terminal illness or cognitive impairment
5. Diagnosed with acute kidney injury on index admission or eGFR < 30
6. Cause for hypertension being toxicology, medical or recreational e.g. amphetamines and their derivatives or alcohol withdrawal syndrome
7. Post discharge destination being one of another hospital, medical treatment facility or prison
8. Receiving concomitant chemotherapy
9. Already recruited to a separate hypertension study
10. Presence of atrial fibrillation or another pulse irregularity which means automated blood pressure monitoring is not appropriate

Date of first enrolment
01/09/2019

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Unviersity Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
South Warwickshire NHS Foundation Trust
Warwick Hospital
Lakin Road
Warwick
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CV34 5BW

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
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Sponsor information

Organisation
Clinical Trials and Research Governance - University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health research Oxford Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2019	05/12/2019	Yes	No
HRA research summary			26/07/2023	No	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