

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
20/08/2019	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
18/11/2019	Ongoing	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
20/01/2026	Circulatory System	

## 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 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

### Contact name

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Scientific

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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

**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  $\geq 18$  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  $\geq$  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**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

351

**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 University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

Headington

Oxford

England

OX3 9DU

**Study participating centre**

**South Warwickshire NHS Foundation Trust**

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**Study participating centre**

**Royal Berkshire NHS Foundation Trust**

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## Sponsor information

**Organisation**

**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**

**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?
<a href="#">Results article</a>		19/01/2026	20/01/2026	Yes	No
<a href="#">Protocol article</a>	protocol	01/12/2019	05/12/2019	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes