

# OUTREACH study: Urine analysis and antihypertensive treatment

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>04/12/2017   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>07/12/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>16/10/2024       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

High blood pressure (also called hypertension) is a condition that affects more than 1 in 4 adults. It can strain the heart and the blood vessels, and increase the risk of stroke, heart attack, heart failure, kidney damage, and death. Failure to take medication as prescribed (i.e. non-adherence) is believed to be common in hypertension because it rarely has noticeable symptoms. The patients recruited in this study will be asked to provide a urine sample at the hypertension clinic to find out if they take their blood pressure medication as prescribed. A group of non-adherent patients participate in a simple 5-step (Discuss/Explore/Act/Co-operate/Reinforce) intervention in which the patient and the treating doctor will discuss the test result, the reasons for not taking the medication as prescribed, and useful measures to improve adherence. The aim of this study is to test if the 5-step intervention helps non-adherent patients to comply with their treatment and lower their blood pressure.

### Who can participate?

Adults aged 18 and older who are taking medications for hypertension.

### What does the study involve?

Participants taking part in the study will be asked to provide urine samples (four in total), to complete some questionnaires (on three occasions) and also to take an automatic monitor home to check their blood pressure three times in the morning and three times in the evening over a period of seven days (on four occasions). The home-based blood pressure monitors and diaries are returned to the hospital. Adherence, health outcomes and care costs are measured and compared with groups of non-adherent and adherent patients who did not receive the intervention.

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

There is no guarantee that this trial will help participants directly but the information obtained from this study may help improve the treatment of people who suffer from high blood pressure and are at risk of heart disease. The potential benefit of this study will be that hypertensive patients at risk of heart disease may be able to be assessed, diagnosed and treated better. Study participants will have to attend additional visits, however, a study voucher will be offered to use at the hospital when attending the visits related to the study (parking costs and refreshments).

Participants may experience local discomfort on the arm when using the home-based blood pressure monitor if the cuff is of the incorrect size or over-inflated. Instructions on how to use the monitor will be provided by the nurse at each visit to reduce the risk.

Where is the study run from?  
University of Manchester (UK)

When is the study starting and how long is it expected to run for?  
September 2017 to September 2023

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

Who is the main contact?  
Marta Ahmed (Project Manager)  
OUTREACH1@manchester.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Marta Ahmed

**Contact details**  
Project Manager  
The University of Manchester  
AV Hill Building  
Upper Brook Street  
Manchester  
United Kingdom  
M13 9LJ  
+44 (0)161 275 1227  
OUTREACH1@manchester.ac.uk

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
229352

**ClinicalTrials.gov (NCT)**  
NCT03293147

**Protocol serial number**  
CPMS 36591, IRAS 229352

# Study information

## Scientific Title

BiOmarkers in Urine, anTiHypeRtensive trEAatment and blood pressure Control in Hypertensive patients - OUTREACH Study

## Acronym

OUTREACH

## Study objectives

The study hypothesis is that providing partially or totally non-adherent hypertensive patients with information on their biochemical adherence test (HPLC-MS/MS-based urine test) combined with tailored targeting of the main reason(s) for the deviation from the prescribed antihypertensive treatment (HPLC-MS/MS-guided intervention), is superior to standard clinical care in improving clinical, behavioural and health-economy outcomes in hypertensive patients who are non-adherent to antihypertensive treatment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 20/12/2017, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ; Email: nrescommittee.northwest-gmsouth@nhs.net), REC ref: 17/NW/0637

## Study design

Randomized; Interventional; Design type: Treatment, Management of Care

## Primary study design

Interventional

## Study type(s)

Prevention

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

Hypertension

## Interventions

The study is a prospective multi-centre randomised controlled trial.

Patient adherence to antihypertensive treatment is determined at baseline using an HPLC-MS/MS-based urine test. Participants taking part in the study are asked to sign a consent form and are required to attend up to five visits to the hospital outpatient clinic over the course of 1 year.

Non-adherent hypertensive patients at baseline are randomised in a 1:1 ratio to either usual clinical care plus HPLC-MS/MS-guided intervention (Arm A) or usual clinical care only (Arm B). The study also evaluates a cohort of patients who are adherent to antihypertensive treatment at baseline. Those adherent hypertensive patients receive the usual clinical care (Arm C). The main

purpose of involving this group of patients is to blind the clinical research staff to the adherence status of those patients randomised receiving standard care alone, to prevent introducing any bias in treating non-adherent patients.

Patients allocated to arm A receive at visit 3 the HPLC-MS/MS-guided intervention (the study intervention) which consists of providing patients with information on the results of their HPLC-MS/MS-based urine analysis combined with tailored targeting of the main reason(s) for the deviation from the prescribed antihypertensive treatment.

Patients allocated to arm B or arm C receive standard care for hypertensive patients at visit 3.

Previous:

All participants are followed-up 3 months and 9 months after the intervention at visit 4 (short-term follow-up) and visit 5 (long-term follow-up) respectively.

Updated 11/03/2021:

All participants are followed-up approximately 12 weeks and 20 weeks after the intervention at visit 4 (short-term follow-up) and visit 5 (long-term follow-up) respectively, or at first availability.

## **Intervention Type**

Other

## **Primary outcome(s)**

Mean clinic systolic blood pressure (SBP) is measured in clinic with the study M3 blood pressure monitor at baseline and visit 4.

## **Key secondary outcome(s)**

1. Mean clinic systolic blood pressure (SBP) is measured in clinic with the study M3 blood pressure monitor at baseline and visit 5
2. Mean clinic diastolic blood pressure (DBP) is measured in clinic with the study M3 blood pressure monitor at baseline, visit 4 and visit 5
3. Mean daytime systolic blood pressure is measured in at home over a 7 days period with the study M3 blood pressure monitor at baseline, visit 4 and visit 5
4. Mean daytime diastolic blood pressure is measured in at home over a 7 days period with the study M3 blood pressure monitor at baseline, visit 4 and visit 5
5. Biochemical adherence is measured using the HPLC-MS/MS test on spot urine samples collected at baseline, visit 4 and visit 5
6. Urinary biomarker of target organ damage is measured by the urinary albumin / creatinine ratio (ACR) at baseline, visit 4 and visit 5
7. Patient quality of life is measured with the validated EQ-5D-3L questionnaire at baseline, visit 4 and visit 5
8. Patient wellbeing is measured with validated ICECAP-A at baseline, visit 4 and visit 5
9. The costs of clinical/social care patient is measured with the health care resource patient questionnaire (including primary and secondary care) at baseline, visit 4 and visit 5

Tertiary outcome measures:

1. Adherence conversion rate is measured the HPLC-MS/MS test on spot urine samples collected at baseline and visit 2
2. Patient's psychological profile is assessed by several questionnaires at baseline, visit 4 and visit 5:
  - 2.1. Patient's anxiety and depression profile is measured by the Hospital anxiety and depression

Score (HADS)

2.2. Patient's perception of their illness is measured by the Brief illness perception questionnaire (B-IPQ)

2.3. Patient's self-reported adherence to antihypertensive medications is measured by the Medication Adherence Report scale (MARS-5)

2.4. Patient's main beliefs influencing antihypertensive medications intake is measured by the Belief about medicines questionnaire specific to hypertension (BMQ-Specific-11-hypertension) and the Belief about medicines questionnaire general combined with the perceived sensitivity to medicines (combined BMQ G12 & PSM)

2.5. Patients' perceptions of the intrusiveness of antihypertensive medications is measured by the Treatment Intrusiveness Scale (TIS)

### **Completion date**

30/09/2023

## **Eligibility**

### **Key inclusion criteria**

1. Male or female aged 18 years or above (min age 18 years old; no maximum age)
2. Patients previously diagnosed with and pharmacologically managed for hypertension
3. Patients with antihypertensive treatment with at least two antihypertensive medications
4. Patients willing and able to give informed consent for study inclusion including all study assessments

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

879

### **Key exclusion criteria**

Current exclusion criteria as of 07/12/2022:

1. Recent history of admission to hospital relating to their hypertension or treatment with antihypertensive medications (< 2 weeks of baseline visit, including admission to A&E)
2. Refusal for 7-day home-based blood pressure monitoring
3. Self-reported pregnancy or breastfeeding
4. Female patients planning to conceive within the next 6 months

Previous exclusion criteria from 11/03/2021 to 07/12/2022:

1. Recent history of admission to hospital relating to their hypertension or treatment with antihypertensive medications (< 2 weeks of baseline visit, including admission to A&E)
2. Refusal for 7-day home-based blood pressure monitoring
3. Self-reported pregnancy or breastfeeding
4. Female patients planning to conceive within the next 12 months

Original exclusion criteria:

1. Recent history of admission to the hospital (<2 weeks of baseline visit, including admission to A&E)
2. Recent change in the prescribed antihypertensive medications (<2 weeks of baseline visit). Changes in antihypertensive drug dose are not considered an exclusion criterion if this is the only change within 2 weeks of the baseline visit
3. Refusal for 7-day home-based blood pressure monitoring
4. Self-reported pregnancy or breastfeeding
5. Female patients planning to conceive within the next 12 months

**Date of first enrolment**

18/12/2018

**Date of final enrolment**

04/02/2023

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

**Manchester Royal Infirmary**

Oxford Road

Manchester

United Kingdom

M13 9WL

**Study participating centre**

**Glenfield General Hospital**

Grobby Road

Leicester

United Kingdom

LE3 9QP

**Study participating centre**  
**St Thomas' Hospital**  
Westminster Bridge Road  
Lambeth  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**Ninewells Hospital**  
James Arrott Drive  
Dundee  
United Kingdom  
DD2 1SY

**Study participating centre**  
**Epsom & St. Helier University Hospital**  
Epsom  
United Kingdom  
KT17 1HB

**Study participating centre**  
**Homerton University Hospital**  
Homerton Row  
London  
United Kingdom  
E9 6SR

**Study participating centre**  
**Royal Free Hospital**  
Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre**  
**St Bartholomew's Hospital**  
William Harvey Heart Centre  
Barts and The London School of Medicine and Dentistry  
Charterhouse Square

London  
United Kingdom  
EC1M 6BQ

**Study participating centre**

**UCLH**

250 Euston Road  
London  
United Kingdom  
NW1 2PQ

**Study participating centre**

**Chilwell Valley and Meadows Practice**

Chilwell Meadows Surgery  
Ranson Road  
Chilwell  
Nottingham  
United Kingdom  
NG9 6DX

**Study participating centre**

**Alvaston Medical Centre**

14 Boulton Lane  
Alvaston  
Derby  
United Kingdom  
DE24 0GE

**Study participating centre**

**University Hospitals Dorset NHS Foundation Trust**

Management Offices  
Poole Hospital  
Longfleet Road  
Poole  
United Kingdom  
BH15 2JB

## **Sponsor information**

**Organisation**



The University of Manchester

ROR

<https://ror.org/027m9bs27>

## 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 and/or analysed during the current study during this study will be included in the subsequent results publication.

### IPD sharing plan summary

Other

### Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <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             |