

Diagnosing and treating severe hypertension

Submission date 24/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/03/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

High blood pressure (hypertension) affects over 1 billion people and, due to its effects on blood vessels, contributes to causes of death worldwide more than any other factor. The risk can be lowered in these patients by reducing blood pressure to target (i.e. recommended) levels set by experts. However, despite the potential benefit to their health, less than half of people treated reach their blood pressure targets. Previous research has shown that the number of patients achieving these goals can be increased by clinics following a clear treatment plan. It has also been shown that early reduction of blood pressure in these patients improves long term health. We aim to show that these findings can be combined using an innovative treatment plan to reduce blood pressure quickly in newly-diagnosed patients with severe hypertension to prove that this is safe and works well. Using this new treatment plan, the study will explore if it is possible to predict whether blood pressure treatment will work before medications are started. Patients will have both non-invasive and simple blood tests to determine their blood vessel and heart structure and function at their first visit. It is hoped that this will help tailor blood pressure treatment to individual patients' needs in the future.

Who can participate?

Adults aged 18-79 recently diagnosed with severe hypertension.

What does the study involve?

All participants receive nurse-led treatment of their hypertension according to a detailed protocol and in-line with current NICE and ESC guidance. This includes 10 visits over an 18-week period in which treatment may be altered depending on individual tolerance and efficacy (how well it works). Before treatment has started, participants have non-invasive tests of their heart and blood vessel structure and function to determine if the results can predict response to treatment. Following completion of the study, participants are discharged to their GP with an ongoing plan for continuing care, or follow-up in the NHS specialist hypertension clinic, depending on clinical need.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Royal Devon & Exeter Hospital, NIHR Exeter Clinical Research Facility MRI Suite and Patient identification centres run by the Devon Partnership NHS Trust (UK)

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

June 2015 to November 2016

Who is funding the study?

Gawthorn Cardiac Trust (UK)

Who is the main contact?

Dr Andrew Jordan

Contact information

Type(s)

Scientific

Contact name

Dr Andrew Jordan

ORCID ID

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Contact details

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Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Additional identifiers

Protocol serial number

19176

Study information

Scientific Title

Understanding the barriers to successful treatment of newly diagnosed severe hypertension: an interventional study

Acronym

DASHER

Study objectives

A study exploring whether a new nurse-led treatment protocol can successfully treat patients with a new diagnosis of severe hypertension within 18 weeks, whilst examining the reasons for failure to achieve blood pressure goals in this cohort.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South West – Cornwall & Plymouth, 17/04/2015, ref: 15/SW/0077

Study design

Interventional

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular Prevention

Interventions

All participants will receive nurse-led treatment of newly-diagnosed severe hypertension according to a detailed protocol and in-line with current NICE and ESC guidance. This includes 10 visit over an 18-week period in which treatment may be altered depending on individual tolerance and efficacy. Before treatment has started, participants will have non-invasive tests of their heart and cardiac and microvascular structure and function to determine if these parameters can predict response to treatment. Following completion of the study, participants will be discharged to their primary care practitioner with an ongoing plan for continuing care, or follow-up in the NHS specialist hypertension clinic, depending on clinical need.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

The proportion of patients with a new diagnosis of severe hypertension who achieve a BP target of <140/90 at 18 weeks.

Key secondary outcome(s)

1. The proportion of patients not reaching target BP who are found to be non-adherent to treatment using directly observed therapy (DOT) and urinary panel testing
2. The incidence of secondary causes of hypertension in the patient cohort
3. Relationship between baseline physiological parameters and success in achieving BP target
4. Proportion of patients enrolled discontinuing the protocol before week 18 and incidence of adverse events during study participation (tolerability)

5. The median number of weeks needed to achieve target blood pressure in the study population
6. Change in CMR findings after successful treatment of severe hypertension as compared to patients in whom treatment is unsuccessful in achieving target BP

Completion date

07/11/2016

Eligibility

Key inclusion criteria

1. New diagnosis of severe hypertension with systolic blood pressure greater than or equal to 170mmHg on screening and when repeated by the study team using the standard operating procedure for blood pressure measurement
2. No present or historical anti-hypertensive agent prescription
3. Aged 18-79 years inclusive

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

79 years

Sex

All

Key exclusion criteria

1. Inability to give informed consent
2. Significant renal dysfunction as defined by eGFR <60 ml/min/1.73m² by Modification of Diet in Renal Disease Study (MDRD) formula
3. Previous or current prescription of any medication used in the study protocol
4. Previous renal artery intervention
5. Bleeding diathesis
6. Haemoglobin <10 g/dl
7. Platelet count <100 x10⁹/l
8. Inability to provide informed consent
9. Pregnancy
10. Hypertension related event (including stroke or acute kidney injury) within the preceding 3 months.
11. Any condition, including hypertensive urgency, which requires more immediate BP lowering or tailored anti-hypertensive strategy at enrolment

Date of first enrolment

23/06/2015

Date of final enrolment

07/11/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Royal Devon & Exeter Hospital (Wonford) - lead site**

Diabetes and Vascular Health Research Centre

Royal Devon & Exeter Hospital

Barrack Road

Exeter

United Kingdom

EX2 5DW

Study participating centre**NIHR Exeter Clinical Research Facility MRI Suite**

St Luke's Campus

University of Exeter

Exeter

United Kingdom

EX1 2LU

Study participating centre**Devon Partnership NHS Trust**

Patient identification centres (PICs)

Exeter

United Kingdom

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Sponsor information

Organisation

Royal Devon & Exeter Hospital

ROR

<https://ror.org/03jrh3t05>

Funder(s)

Funder type

Charity

Funder Name

Gawthorn Cardiac Trust (UK)

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?
Results article	Participant information sheet	25/10/2021	26/10/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		04/03/2022	07/03/2022	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes