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Diagnosing and treating severe hypertension

Submission date	Recruitment status	[ ] Prospectively registered
24/06/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/03/2022	Circulatory System	

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

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Contact details
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Exeter
United Kingdom
EX2 5DW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
23/06/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
79 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

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
England

United Kingdom

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

Sponsor details
Cancer Clinical Trials
Cherrybrook Ward
Cancer Clinical Trials
Room S142
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jrh3t05

Funder(s)

Funder type
Charity

Funder Name
Gawthorn Cardiac Trust (UK)

Results and Publications

Publication and dissemination plan

The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study, the details of which will depend on the study results. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. Participants will be given access to the final published findings of the study on request. Time will be allocated for publication and dissemination of results at the end of the study period (March-November 2016).

Intention to publish date
01/11/2016

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		25/10/2021	26/10/2021	Yes	No
Other publications		04/03/2022	07/03/2022	Yes	No
HRA research summary			28/06/2023	No	No