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Does the underlying haemodynamic abnormality determine response to antihypertensive therapy?

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 04/08/2016	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2006-006981-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5293

Study information

Scientific Title
Does the underlying haemodynamic abnormality determine response to antihypertensive therapy?

Acronym
Rotation Study

Study objectives
The purpose of the study/trial is to find out the relation of haemodynamic abnormalities in 60 patients with hypertension and their responses to different classes of antihypertensive agents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 07/Q0108/33

Study design
Single-centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Patients will be enrolled and the following data is collected:
1. History
2. Physical examination
3. Height
4. Weight
5. Blood tests
6. Electrocardiogram (ECG)
7. Haemodynamic measurements

Administration of medications will be in a double-blind randomised placebo controlled cross-over methodology: doxazosin 1 - 4 mg, bisoprolol 2.5 - 5 mg, candesartan 8 - 16 mg, isosorbide mononitrate M/R 25 - 50 mg

There will be 42 days per treatment phase and 36 weeks in total.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Doxazosin, bisoprolol, candesartan, isosorbide mononitrate

Primary outcome measure
Difference in BP change according to pre-specified group analysis.

Secondary outcome measures
1. Change in haemodynamic parameters achieved by different study medication
2. Number of patients reaching target BP

Overall study start date
01/06/2007

Completion date
01/08/2009

Eligibility

Key inclusion criteria
Hypertensive patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2007

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
Box 277, Hills Road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/research/research_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No