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Pathophysiological mechanisms of hypertensive left ventricular hypertrophy: optimising regression

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 24/09/2012	**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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436117967

Study information

Scientific Title

Study objectives
We aim to investigate the mechanisms responsible for the development of hypertensive left ventricular hypertrophy (LVH), and determine the optimal treatment strategy. We aim to investigate the mechanisms responsible for the development of hypertensive left ventricular hypertrophy (LVH), and determine the optimal treatment strategy. LVH is thought to be related to activation of the renin-angiotensin system and the sympathetic nervous system, in addition to the effect of the high blood pressure. We will accurately determine baseline LV mass using cardiac MRI as well as measuring the degree of humoral and neural activation. Patients will be randomised to different combinations of standard blood pressure treatments for 4 months and then reassessed. We hope to determine whether controlling blood pressure by specifically targeting the neurohumoral activation is more effective in regressing LVH than simple blood pressure control alone. It is hoped that this study will yield useful information regarding the best treatment for hypertensive LVH.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Hypertensive left ventricular hypertrophy (LVH)

Interventions

Laboratory study; Randomised controlled trial, Random allocation to different combinations of standard blood pressure treatments.

Random allocation to:
A. Treatment one
B. Treatment two
C. Treatment three
D. Treatment four

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Magnetic resonance imaging (MRI) measurement of left ventricular mass regression.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2002

Completion date
30/11/2009

Eligibility

Key inclusion criteria
All recruited patients will have hypertension and left ventricular hypertrophy.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2002

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Yorkshire Heart Centre
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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 provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No