Pathophysiological mechanisms of hypertensive left ventricular hypertrophy: optimising regression

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

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