ISRCTN48331653 https://doi.org/10.1186/ISRCTN48331653

Left ventricular hypertrophy: reduction of blood pressure already in the normal range further regresses left ventricular mass

Submission date 23/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/03/2006	**Overall study status** Completed	
Last Edited 09/12/2010	**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
2004CV02

Study information

Scientific Title

Study objectives
Please note that, as of 9th December 2010, the public title of this trial has been changed from "Left ventricular hypertrophy in normotensive individuals: would reducing blood pressure further enhance left ventricular hypertrophy regression? " to "Left ventricular hypertrophy: reduction of blood pressure already in the normal range further regresses left ventricular mass."

There are a significant number of individuals with a normal blood pressure and left ventricular hypertrophy (LVH). Would an extra reduction in blood pressure enhance LVH regression?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, approved by the Tayside Committee on Medical Research Ethics A
REC on 23/07/2004, reference number: 04/S1401/47

Study design
Randomised, single-blind, placebo-controlled

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
Left ventricular hypertrophy

Interventions
Two thirds of patients to receive active medication (normal antihypertensives once daily including: bendroflumethiazide 2.5 mg, amlodipine 5 mg, atenolol 50 mg, doxazosin XL 4 mg, spironolactone 25 mg) to lower blood pressure by 10 mmHg. Remaining third to receive placebo with aim of maintaining blood pressure at levels at start of the trail.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
1. Bendroflumethiazide 2.5 mg once daily 2. Amlodipine 5 mg once daily 3. Atenolol 50 mg once daily 4. Doxazosin XL 4 mg once daily 5. Spironolactone 25 mg once daily

Primary outcome measure
Assess for reduction in left ventricular mass index as calculated from MRI

Secondary outcome measures
Reduction in other markers of cardiovascular risk

Overall study start date
01/03/2005

Completion date
28/02/2007

Eligibility

Key inclusion criteria
1. Normal blood pressure
2. Left ventricular hypertrophy
3. On angiotensin converting enzyme (ACE) inhibitor or angiotensin II (AII) receptor blocker or contraindication to both

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Renal disease
2. Proteinuria
3. Claustrophobia or other contraindication to magnetic resonance imaging (MRI) scanning

Date of first enrolment
01/03/2005

Date of final enrolment
28/02/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Clinical Pharmacology
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovations Services
11 Perth Road
Dundee
United Kingdom
DD1 4HN

Sponsor type
Not defined

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
St Andrews House

Funder Name
Regent Road

Funder Name
Edinburgh

Funder Name
EH1 3DG

Funder Name
CSO grant number: CZB/4/145

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

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 provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No