

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
Registration date 29/03/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/12/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, single-blind, placebo-controlled

Study type(s)

Not Specified

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 trial.

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(s)

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

Key secondary outcome(s)

Reduction in other markers of cardiovascular risk

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Department of Clinical Pharmacology

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

University of Dundee (UK)

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

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