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Comparison of the effect of anti-hypertensive treatment with verapamil and amlodipine on the coronary vasodilator reserve and the transmural distribution of myocardial blood flow in hypertensive patients with left ventricular hypertrophy

Submission date 13/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/11/2005	**Overall study status** Completed	
Last Edited 20/05/2016	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Paolo Camici

Contact details
MRC CSC
Hammersmith Campus
London
United Kingdom
W12 0NN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VER240/1/01

Study information

Scientific Title
Comparison of the effect of anti-hypertensive treatment with verapamil and amlodipine on the coronary vasodilator reserve and the transmural distribution of myocardial blood flow in hypertensive patients with left ventricular hypertrophy

Study objectives
Beneficial effect of calcium antagonists on coronary vasodilator reserve and transmural distribution of flow in hypertensive patients with left ventricular hypertrophy.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
The study will enrol hypertensive patients with a left ventricular septum thickness of 13 mm measured with 2D echocardiogram. The overall duration of the study will be of 13 weeks. The first week will consist of a wash-out/run-in phase, when only diuretic therapy will be allowed.

Thereafter the patients will be assigned following the randomisation list to the double-blinded treatment (group 1: verapamil or matching placebo; group 2: amlodipine or matching placebo).

After a period of 6 weeks of treatment the first positron emission tomography (PET) scan will be performed.

Afterwards, within each group, patients will change double-blind treatment from active drug to matching placebo or vice-versa, for 6 additional weeks at the end of which the second and final PET scan will be performed.

The primary parameter under study i.e. myocardial blood flow, will be measured at rest and after the dipyridamole stress test at the end of each treatment period. Briefly, a radioisotope of water (H2^15O) will be infused through a peripheral vein, subsequently, with the patient lying flat, the scan will be acquired. Once this is completed, dipyridamole is infused via the same catheter for 4 minutes. At the end of the infusion, a further scan with H2^15O will be undertaken. The whole procedure will last approximately 90 minutes. Any treatment for hypertension, except for thiazidic diuretics and phtalimidine derivatives, will not be allowed.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Verapamil, amlodipine

Primary outcome measure
The primary objective of the study is to compare the Coronary Vasodilator Reserve corrected after treatment with verapamil, placebo and amlodipine in hypertensive subjects with left ventricular hypertrophy. With two treatments, two measurements and a within-subject control.

Secondary outcome measures
Reduction of left ventricular mass

Overall study start date
01/03/1998

Completion date
31/01/2005

Eligibility

Key inclusion criteria
1. Blood pressure (measured after 5 minutes in the supine position) 160/100 mmHg based on the mean of 3 recordings within a 1 minute interval
2. Left ventricular septum thickness >=13 mm or left ventricular mass index (LVMI) >=130 g/m2 (men), >=100 g/m2 (women). The measurements will be recorded by echocardiography.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Women of childbearing age without adequate contraception
2. Any documented disease of any of the following systems will be a contraindication to entry into the study: respiratory, renal, digestive, nervous central or peripheral, musculoskeletal, haemolymphopoietic, immune, metabolism
3. Subjects with drug or alcohol addiction

Date of first enrolment
01/03/1998

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC CSC
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Abbott (Germany)

Sponsor details
Knollstrasse 50
Ludwigshafen
Germany
67061

Sponsor type
Industry

ROR
https://ror.org/02x2gk324

Funder(s)

Funder type
Industry

Funder Name
Abbott (Germany)

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