Combination drug treatment in moderate-tosevere essential hypertension

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
19/10/2016	Circulatory System	☐ Record updated in last year

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

ClinicalTrials.gov number

Secondary identifying numbers N0236066889

Study information

Scientific Title

Combination drug treatment in moderate-to-severe essential hypertension

Study objectives

The aim of this study is to investigate the effect on blood pressure of the addition of moxonidine or doxazosin in 20 patients with moderate-to-severe essential hypertension who are not adequately controlled on triple therapy with amlodipine 5-10 mg once daily (o.d.), enalapril 10 mg b.d. and bendrofluazide 5 mg o.d.

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

Only those patients treated for at least one month with amlodipine 5-10mg o.d., enalapril 10-20mg twice daily (b.d.) and bendrofluazide 5mg o.d., will be included in the study if their supine systolic and/or diastolic BP is >160/90 mmHg on two different occasions. A randomised, double-blind, prospective study.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

moxonidine or doxazosin

Primary outcome measure

Control of blood pressure < 150/90 mmHg

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/1999

Completion date

30/09/2005

Eligibility

Key inclusion criteria

Patients with uncomplicated, moderate-to-severe essential hypertension which is not adequately controlled on triple therapy with amlodipine 5-10 mg once daily (o.d.), enalapril 10-20 mg b.d. and bendrofluazide 5 mg o.d., iv)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

Malignant or accelerated hypertension. Serum creatinine >60umol/L, ischaemic heart disease, cerebrovascular disease, impaired liver function, diabetes mellitus, pregnancy or risk of pregnancy, lactation, history of alcoholism, drug abuse or other problems likely to invalidate the informed consent.

Date of first enrolment

01/05/1999

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Blood Pressure Unit London United Kingdom SW17 0QT

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

St George's Healthcare NHS Trust

Funder Name

The Blood Pressure Unit

Funder Name

NHS R&D Support Funding

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration