ISRCTN46173989 https://doi.org/10.1186/ISRCTN46173989

Combination drug treatment in moderate-to-severe 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
Prof Graham A MacGregor

Contact details
Blood Pressure Unit
Jenner Wing
St George's Hospital
Blackshaw Road, Tooting
London
United Kingdom
SW17 0QT
+44 (0)20 8725 2848
g.macgregor@sghms.ac.uk

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 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