

A rotation study through the main therapeutic classes of antihypertensive in patients with polycystic kidney disease and hypertension

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/05/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Kevin M O'Shaugnessy

Contact details

Box No 110
Clinical Pharmacology Unit
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 245151 ext.2894
kmo22@medschl.cam.ac.uk

Additional identifiers

Protocol serial number

N0544099293

Study information

Scientific Title

Study objectives

This will be a study in patients with Polycystic Kidney Disease (PKD) and hypertension designed to evaluate:

1. Individual responsiveness to 5 main drug groups:
 - 1.1. Angiotensin Converting Enzyme (ACE)-inhibitor
 - 1.2. Alpha-blockade
 - 1.3. Beta-blockade
 - 1.4. Diuretic
 - 1.5. Calcium antagonist, and
2. Whether lowering blood pressure improves quality of life, Left Ventricular (LV) mass and endothelial function in PKD patients with mild/moderate hypertension and normal renal function.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular: Hypertension

Interventions

Following a 2-week placebo run-in period, patients eligible to enter this crossover, double-blind study will receive in a randomised order, daily, and for a six week period:

1. Amlodipine (5 mg)
2. Doxazosin (1 mg increasing to 4 mg)
3. Lisinopril (2.5 mg increasing to 10 mg)
4. Benrofluazide (2.5 mg)
5. Bisoprolol (5 mg)
6. Placebo

Patients will then receive an additional six weeks treatment with the agent that produced the greatest lowering of mean supine blood pressure.

Updated 16/05/2014: the trial was stopped in 2008 due to a lack of funding.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Amlodipine, doxazosin, lisinopril, benrofluazide, bisoprolol

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

24/02/2007

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility**Key inclusion criteria**

40 outpatients aged 18 - 65 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

24/02/2000

Date of final enrolment

24/02/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Box No 110

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Cambridge Consortium - Addenbrookes Hospital (UK)

Funder Name

British Heart Foundation (UK)

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

NHS R&D Support Funding (UK) (ref: 2007/08)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration