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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 16/05/2014	**Condition category** Circulatory System	

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
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_bhf, The British Heart Foundation, 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