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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/02/2000

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
40

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
England

United Kingdom

Study participating centre
Box No 110
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.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

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