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Double Blind Crossover Comparison of Diuretics in the Young

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 01/02/2019	**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
NCT00429897

Secondary identifying numbers
3000

Study information

Scientific Title
Double Blind Crossover Comparison of Diuretics in the Young

Study objectives
This clinical trial aims to determine whether low-renin (ie salt sensitive) hypertension at a young age is caused by the kidneys hanging onto too much salt as a result of an over-active salt pump in the kidney. The kidneys have four salt pumps, and each is blocked by a different type of diuretic (salt losing) tablet. If one of the four is overactive we would expect patients to respond much better to one diuretic than to the alternative- rather than responding equally well to all types of diuretic. The study also aims to determine genetic mutations responsible for low-renin hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved on the 7th July 2006 (ref: 06/MRE05/31)

Study design
Single centre randomised interventional treatment 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
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Patients will receive, in a random order, 5 blocks of 5 week treatments consisting of:
1. Bendroflumethiazide 2.5 - 5 mg
2. Amiloride 20 - 40 mg
3. Spironolactone 50 - 100 mg
4. Frusemide 20 - 40 mg
5. A combination of bendroflumethiazide 1.25 - 2.5 mg and amiloride 10 - 20 mg

There will be a forced titration from lower to the higher dose half way through each dosing period. Each phase will start with two days of placebo treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bendroflumethiazide, amiloride, spironolactone, frusemide

Primary outcome measure
Difference in the fall in systolic blood pressure for each participant's best and second best drug

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Aged 18 - 45 years
2. Male or female
3. Hypertensive:
3.1. Three clinic systolic blood pressure (SBP) greater than or equal to 140 mmHg; or
3.2. Three clinic diastolic blood pressure (DBP) greater than or equal to 90 mmHg; or
3.3. Ambulatory blood pressure monitoring (ABPM) or home blood pressure (BP) greater than or equal to 130 mmHg (SBP) or 85 mmHg (DBP)
4. 24-hour Na+ less than 160 mmol/l
5. Either:
5.1. Plasma renin less than or equal to 10 mU/L (measured untreated, or whilst receiving only CCB+/-diuretic) + plasma renin less than or equal to 40 mU/L (measured on an ACEi or ARB, which approximately doubles the plasma renin); or
5.2. Plasma renin less than 5 mU/L (measure untreated)
6. Receiving any antihypertensive drug other than a beta-blocker

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned sample size: 30

Key exclusion criteria
1. Documented history of gout
2. Abnormal renal function (both elevated serum creatinine and reduced creatinine clearance)
3. SBP greater than 170 mmHg or DBP greater than 110 mmHg despite treatment with permitted background treatment

Date of first enrolment
01/08/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Pharmacology Unit
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
Box 277, Hills Road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/research/research_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (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

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