Double Blind Crossover Comparison of Diuretics in the Young

	Prospectively registered
12/05/2010 No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Circulatory System	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00429897

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration