

# Double Blind Crossover Comparison of Diuretics in the Young

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/02/2019	<b>Condition category</b> 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**  
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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<sup>+</sup> 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 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

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration