

# Spironolactone AmiLoride Thiazide study of aldosterone sensitive hypertension

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/03/2002   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>28/03/2002 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>04/07/2007       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data                                              |

**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**  
PG/02/014/13511

## Study information

**Scientific Title**

**Acronym**

SALT

**Study objectives**

Spironolactone will reduce systolic Blood Pressure (sBP) by more than 5 mmHg than bendrofluazide.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval information not required at time of registration.

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Low-renin hypertension

**Interventions**

Spironolactone (50 & 100 mg), amiloride (20 & 40 mg), bendrofluazide (2.5 & 5 mg), irbesartan (150 mg), placebo.

The lower dose of each will be re-encapsulated in identical capsules. Patients will take two capsules each day, consisting of either two placebos, or one each active and placebo (ie low-dose active), or two active (ie high-dose active).

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Spironolactone, amiloride, bendrofluazide and irbesartan.

**Primary outcome(s)**

sBP and plasma renin on spironolactone versus bendroflumethiazide.

**Key secondary outcome(s)**

1. sBP on amiloride versus other diuretics.
2. Further measures of natriuresis.

**Completion date**

01/09/2005

## Eligibility

### Key inclusion criteria

1. Hypertension (requiring treatment according to British Hypertension Society [BHS] criteria)
2. Aldosterone/renin ratio >400
3. Either Systolic Blood Pressure (SBP) on spironolactone more than or equal to 20 mmHg, during previous open-label treatment or Plasma renin activity less than 0.2 pmol/ml/h and response to spironolactone not previously tested

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Not Specified

### Sex

Not Specified

### Key exclusion criteria

Contraindications to study drugs

### Date of first enrolment

01/02/2003

### Date of final enrolment

01/09/2005

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Clinical Pharmacology Unit

Cambridge

United Kingdom

CB2 2QQ

## Sponsor information

**Organisation**

British Heart Foundation (UK)

**ROR**

<https://ror.org/02wdwnk04>

## Funder(s)

**Funder type**

Charity

**Funder Name**

British Heart Foundation (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

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | Results | 17/07/2007   |            | Yes            | No              |