Spironolactone AmiLoride Thiazide study of aldosterone sensitive hypertension

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
28/03/2002		Protocol		
Registration date 28/03/2002	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 04/07/2007	Condition category Circulatory System	[] Individual participant data		

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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

Drug/device/biological/vaccine name(s)

Spironolactone, amiloride, bendrofluazide and irbesartan.

Primary outcome measure

sBP and plasma renin on spironolactone versus bendroflumethiazide.

Secondary outcome measures

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

Overall study start date

01/02/2003

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

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

England

United Kingdom

Study participating centre Clinical Pharmacology Unit

Cambridge United Kingdom CB2 2QQ

Sponsor information

Organisation

British Heart Foundation (UK)

Sponsor details

14 Fitzhardinge Street London United Kingdom W1H 6DH +44 (0)20 7935 0185 research@bhf.org.uk

Sponsor type

Charity

Website

http://www.bhf.org.uk/

ROR

https://ror.org/02wdwnk04

Funder(s)

Funder type

Charity

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	17/07/2007		Yes	No