ISRCTN85520592 https://doi.org/10.1186/ISRCTN85520592

Spironolactone AmiLoride Thiazide study of aldosterone sensitive hypertension

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Morris J Brown

Contact details
Clinical Pharmacology Unit
Level 6 ACCI
Box 110
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 336743
mjb14@medschl.cam.ac.uk

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

Not Specified

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