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Double blind, randomised controlled cross over trial comparing the antihypertensive effects of amiloride and spironolactone in black hypertensives with and without the T594M mutation

Submission date 08/03/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 08/03/2002	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/03/2017	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PG/2001084

Study information

Scientific Title
Double blind, randomised controlled cross over trial comparing the antihypertensive effects of amiloride and spironolactone in black hypertensives with and without the T594M mutation

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided 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)
Not Specified

Participant information sheet

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

Interventions
1. Amiloride 5 mg bd for 2 weeks, increased to 10 mg bd for further 6 weeks. Then cross over to spironolactone as below, then to a combination of amiloride 5 mg bd plus spironolactone 25 mg bd
2. Spironolactone 25 mg bd for 2 weeks then increased to 50 mg bd for further 6 weeks. Then cross over to amiloride as above, then to a combination of amiloride 5 mg bd plus spironolactone 25 mg bd

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
amiloride and spironolactone

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Hypertensives of African origin
2. Subjects with the T594M polymorphism and controls with the wild-type sodium channel

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Blood Pressure Unit
London
United Kingdom
SW17 0RE

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