

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Blood Pressure Unit

London

United Kingdom

SW17 0RE

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