

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

<b>Submission date</b> 08/03/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/03/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/03/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr PA Swift

**Contact details**  
Blood Pressure Unit  
Department of Physiological Medicine  
St George's Hospital Medical School  
Cranmer Terrace  
London  
United Kingdom  
SW17 0RE  
+44 20 8725 3176  
pswift@sghms.ac.uk

## 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