

Does aldosterone blockade improve endothelial dysfunction in patients with coronary artery disease but without heart failure?

Submission date 21/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/03/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/01/2014	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

Dr Nimit Shah

Contact details

Department of Clinical Pharmacology
Level 7
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Additional identifiers

Protocol serial number

Sha001

Study information

Scientific Title

Study objectives

Aldosterone blockade improves endothelial function in patients with coronary artery disease without heart failure

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Regional Research Ethics Committee on 09/07/2004, reference number: 04/S1401/82

Primary study design

Interventional

Study design

Randomised, double-blind, placebo-controlled crossover trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions

Spironolactone versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Spironolactone

Primary outcome(s)

Improvement in endothelial function

Key secondary outcome(s)

1. Changes in brain natriuretic peptide (BNP)
2. Amino-terminal propeptide of type III procollagen (PIIINP)
3. Angiotensin converting enzyme (ACE) activity
4. Heart rate variability
5. QT dispersion

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Patient with known coronary artery disease
2. Chronic stable angina

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Left ventricular systolic dysfunction
2. Renal failure
3. Hyperkalaemia
4. Warfarin therapy

Date of first enrolment

05/01/2005

Date of final enrolment

31/12/2006

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

Department of Clinical Pharmacology

Dundee

United Kingdom

DD1 9SY

Sponsor information**Organisation**

University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Charity

Funder Name

British Hearth Foundation

Results and Publications

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	01/11/2007		Yes	No