ISRCTN70010120 https://doi.org/10.1186/ISRCTN70010120

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/03/2006	**Overall study status** Completed	
Last Edited 02/01/2014	**Condition category** Circulatory System	

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
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

Study design
Randomised, double-blind, placebo-controlled crossover 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
Coronary artery disease

Interventions
Spironolactone versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Spironolactone

Primary outcome measure
Improvement in endothelial function

Secondary outcome measures
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

Overall study start date
05/01/2005

Completion date
31/12/2006

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
88

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
Scotland

United Kingdom

Study participating centre
Department of Clinical Pharmacology
Dundee
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Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
British Hearth Foundation

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	01/11/2007		Yes	No