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Effect of epleronone on thrombotic and thrombolytic status in heart failure and coronary artery disease

Submission date 04/09/2006	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/10/2006	**Overall study status** Stopped	
Last Edited 06/01/2011	**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

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
Epleronone attenuates platelet reactivity, and enhances endogenous fibrinolytic status in patients with Heart Failure (HF) and Coronary Artery Disease (CAD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application submitted to Hertfordshire 2 Research Ethics Committee (REC Ref: 06/Q0204/102), next meeting due 11 November 2006.

Study design
Prospective, double-blind, randomised study with a cross-over design.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart Failure and Coronary Artery Disease

Interventions
Epleronone or placebo

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
The primary end-point within each group will be the change in platelet reactivity and thrombolytic status from baseline, following treatment with epleronone.

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/10/2007

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
1. Aged 18 to 80 years
2. Stable documented CAD or stable HF (functional state New York Heart Association Class II or III) and healthy volunteers

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to consent
2. Current participation in another study
3. Over 80 years and under 18 years
4. Acute coronary syndrome within four weeks
5. Acute hospital admission with HF in preceding four weeks
6. Stroke in the last four weeks
7. Insulin-dependent diabetes mellitus
8. Renal impairment
9. Sepsis
10. Malignancy
11. Bleeding diathesis
12. Concomitant medication with clopidogrel, erythromycin, dipyridamole, warfarin, glycoprotein 2b/3a inhibitors, epleronone, spironolactone or angiotensin II antagonists
13. When complete follow up over one week period in the judgment of the investigator is unlikely
14. Any disease shortening life-expectancy to less than 12 months
15. Blood dyscrasia
16. Intolerance to or contra-indication to aspirin
17. Any contra-indication to Epleronone

Date of first enrolment
01/11/2006

Date of final enrolment
30/10/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cardiology Department
Welwyn Garden City
United Kingdom
AL7 4HQ

Sponsor information

Organisation
East and North Hertfordshire NHS Trust (UK)

ROR
https://ror.org/02ryc4y44

Funder(s)

Funder type
Government

Funder Name
Local Research and Development funding from East and North Hertfordshire NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration