

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

Submission date 04/09/2006	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/10/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/01/2011	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

105

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

England

United Kingdom

Study participating centre**Cardiology Department**

Welwyn Garden City

United Kingdom

AL7 4HQ

Sponsor information

Organisation

East and North Hertfordshire NHS Trust (UK)

Sponsor details

Howlands

Welwyn Garden City

England

United Kingdom

AL7 4HQ

Sponsor type

Hospital/treatment centre

Website

<http://www.enherts-tr.nhs.uk/default.htm>

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

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