

A randomised, double-blinded, placebo-controlled trial using cardiovascular magnetic resonance (CMR) scanning to assess remodelling and regression of fibrosis in cardiomyopathy with eplerenone

Submission date 28/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/10/2017	Condition category Circulatory System	☐ Individual participant data ☐ 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

Protocol serial number
N0201163398

Study information

Scientific Title

A randomised, double-blinded, placebo-controlled trial using cardiovascular magnetic resonance (CMR) scanning to assess remodelling and regression of fibrosis in cardiomyopathy with eplerenone

Study objectives

To demonstrate regression of fibrosis in patients with cardiomyopathy who are treated with eplerenone using cardiovascular magnetic resonance. This trial compares patients taking the drug eplerenone with patients who don't and whether it reduces the amount of fibrosis (scarring) of the heart.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Riverside Research Ethics Committee Charing Cross Hospital (UK), 09/10/2006, ref 06/Q0401/50

Study design

Randomised double-blinded placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular: Cardiomyopathy

Interventions

Eplerenone vs placebo

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Eplerenone

Primary outcome(s)

Reduction in amount of fibrosis as determined by CMR Late enhancement

Key secondary outcome(s)

1. Improvement in myocardial oxygen consumption (MVO₂)
2. Reduction in major adverse cardiovascular events

Completion date

26/10/2008

Eligibility

Key inclusion criteria

Stable patients with an established diagnosis of cardiomyopathy as assessed by history, examination and typical ECG/Echo findings who are on maximally tolerated doses of appropriate drugs with no changes being made to the prescription in the 2 months preceding the start of the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients already established on treatment with an aldosterone antagonist
2. Patients with contraindications to eplerenone (hyperkalaemia, renal failure)
3. Critically ill patients requiring respiratory and/or circulatory support
4. Pacemaker or ICD
5. Implanted ferromagnetic cerebrovascular clips
6. Pregnant women (precautionary only)
7. Intolerance of confined spaces
8. Inability to lie supine for 60 minutes
9. Unwilling or unable to give written informed consent
10. Atrial fibrillation or ventricular bigeminy
11. Any contraindication to CMR.
12. Recent MI
13. HCM patients who have received surgical/alcohol ablation treatment

Date of first enrolment

27/10/2006

Date of final enrolment

26/10/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Royal Brompton & Harefield NHS Trust
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Royal Brompton and Harefield NHS Trust (UK), No External Funding, NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration