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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

Registration date
28/09/2007

Overall study status
Completed

Last Edited
12/10/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes