ISRCTN23314770 https://doi.org/10.1186/ISRCTN23314770

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Reduction in amount of fibrosis as determined by CMR Late enhancement

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

Overall study start date
27/10/2006

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

Age group
Adult

Sex
Both

Target number of participants
140

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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