

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/10/2017	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

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