

Metabolic Manipulation in chronic heart failure

Submission date 19/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/10/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00841139

Protocol serial number
3741

Study information

Scientific Title
Metabolic changes induced by perhexiline versus placebo on myocardial metabolism in chronic heart failure: a multicentre randomised interventional treatment trial

Study objectives

We wish to investigate the metabolic changes induced by perhexiline on myocardial metabolism in chronic heart failure. Perhexiline has been shown to improve exercise capacity in this group of patients. Perhexiline is thought to work by increasing carbohydrate metabolism and reducing fatty acid metabolism leading to improved metabolic efficiency. We plan to investigate myocardial metabolism both invasively and non-invasively to demonstrate these changes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Birmingham REC approved on the 12th May 2006 (ref: 06/Q2707/7)

Study design

Multicentre randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

Perhexiline/Placebo 100 mg orally twice daily (bd) randomised in a 50:50 fashion with drug dose titration in accordance with serum levels.

Total duration of follow-up: one month

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Improvement in PCr/ATP ratio

Key secondary outcome(s)

1. Change in mechanical efficiency (external work/ MVO₂)
2. Change in respiratory quotient

Completion date

04/09/2009

Eligibility

Key inclusion criteria

1. Aged greater than 18 years, no upper limit, either sex
2. Optimally medicated dilated cardiomyopathy
3. Symptomatic (New York Heart Association [NYHA] II - III)
4. Ejection fraction (EF) less than 40%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Implanted cardiac devices
2. Body mass index (BMI) greater than 32
3. Renal impairment
4. Liver function test abnormalities
5. Use of amiodarone
6. Selective serotonin reuptake inhibitor (SSRI) medications or haloperidol

Date of first enrolment

04/09/2006

Date of final enrolment

04/09/2009

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Edgbaston

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University Hospitals Birmingham NHS Foundation Trust (UK)

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (BHF) (UK)

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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?
Results article	results	01/03/2015		Yes	No
Protocol article	protocol	06/06/2011		Yes	No