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Metabolic Manipulation in chronic heart failure

Submission date 19/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/05/2010	**Overall study status** Completed	
Last Edited 01/10/2018	**Condition category** Circulatory System	

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 ivestigate 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 demonstate 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_bhf, The British Heart Foundation, 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes