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Randomised double-blind controlled trial of Perhexiline in heart failure with preserved ejection fraction syndrome (HFpEF)

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 02/10/2017	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7196

Study information

Scientific Title
Randomised double-blind controlled trial of Perhexiline in heart failure with preserved ejection fraction syndrome (HFpEF)

Acronym
Perhexiline in HFpEF

Study objectives
This study is investigating the effect of perhexiline on patients with heart failure and preserved ejection fraction (HFpEF). Heart failure is a condtion that is defined by the heart's impaired energetic status. the trialists hypothesise that by improving the heart's energetic staus with the metabolic modulating drug perhexiline, we will improve the patients exercise capacity. This improvement in exercise capacity will be due to improved cardiac energetics and improved diastolic function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H1207/84)

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Interventions
Perhexiline/placebo randomised in a 50:50 fashion. The perhexiline is started at 100 mg per oral twice daily (bd) and titrated according to serum levels. The medication is ceased after 3 months of therapy.

Follow-up length: 3 months
Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Perhexiline

Primary outcome measure
Peak oxygen consumption (VO2 max)

Secondary outcome measures
Symptomatic status (Modified Minnesota Living with Heart Failure Questionnaire)

Overall study start date
01/03/2009

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Heart failure normal ejection fraction diagnosed by signs or symptoms of heart failure and limitation on metabolic exercise testing

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 50

Key exclusion criteria
1. Renal or liver impairment
2. Atrial fibrillation
3. Contraindication to magnetic resonance imaging (MRI)
4. Contraindication to perhexiline

Date of first enrolment
01/03/2009

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

Sponsor details
Department of Cardiothoracic Surgery
Edgbaston
Birmingham
England
United Kingdom
B15 2PR

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.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

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