

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/10/2017	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

Contact name

Mr Roger Beadle

Contact details

Department of Cardiovascular Medicine
Medical School
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

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 condition that is defined by the heart's impaired energetic status. The trialists hypothesise that by improving the heart's energetic status 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