

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

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 02/10/2017	<b>Condition category</b> 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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

Peak oxygen consumption (VO2 max)

**Key secondary outcome(s)**

Symptomatic status (Modified Minnesota Living with Heart Failure Questionnaire)

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

University of Birmingham  
Birmingham

United Kingdom  
B15 2TT

## Sponsor information

### Organisation

University Hospital 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