

# A single centre, placebo controlled trial to investigate the safety and tolerability of bisoprolol in patients with chronic heart failure and chronic obstructive pulmonary disease

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/10/2017	<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

### Contact name

Dr AJ Cowley

### Contact details

Cardovascular Medicine  
D Floor, South Block  
University Hospital  
Nottingham  
United Kingdom  
NG7 2UH

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

A single centre, placebo controlled trial to investigate the safety and tolerability of bisoprolol in patients with chronic heart failure and chronic obstructive pulmonary disease

### Study objectives

1. Is bisoprolol safe and well tolerated in patients with heart failure and chronic obstructive pulmonary disease?
2. What effects does bisoprolol have on neurohormones in patients with heart failure?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Cardiovascular: Heart failure

### Interventions

Randomised controlled trial.

### Intervention Type

Drug

### Phase

Not Specified

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

bisoprolol

**Primary outcome measure**

1. a significant deterioration in spirometry (forced expiratory volume in one second [FEV1]) measurements
2. the levels of several neurohormones in heart failure patient's blood

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

17/05/2003

**Completion date**

30/08/2004

**Eligibility****Key inclusion criteria**

Total number of subjects = 20.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

20

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

17/05/2003

**Date of final enrolment**

30/08/2004

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Cardovascular Medicine**  
Nottingham  
United Kingdom  
NG7 2UH

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Nottingham University Hospitals NHS Trust (UK)

## **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