# 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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
13/10/2017	Circulatory System	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