

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

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Contact details

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Additional identifiers

Protocol serial number

N0192107572

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/08/2004

Eligibility

Key inclusion criteria

Total number of subjects = 20.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Cardiovascular Medicine

Nottingham

United Kingdom

NG7 2UH

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Nottingham University Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration