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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

Registration date
12/09/2003

Last Edited
13/10/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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

Primary study design
Interventional

Study design
Randomised controlled trial

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
Cardovascular 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