ISRCTN77645264 https://doi.org/10.1186/ISRCTN77645264

A pilot study to assess the effect of beta blockade on exercise capacity and BNP levels in patients with predominantly diastolic heart failure

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/10/2016	**Condition category** Circulatory System	[_] 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
N0226167747

Study information

Scientific Title
A pilot study to assess the effect of beta blockade on exercise capacity and BNP levels in patients with predominantly diastolic heart failure

Study objectives
Does the use of beta-blockers in patients with diastolic dysfunction and preserved systolic function result in a significant improvement in quality of life and exercise capacity, a significant reduction in plasma BNP levels, and improved CRP and interleukin levels?

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)
Quality of life

Health condition(s) or problem(s) studied
Cardiovascular: Heart failure

Interventions
1. Bisoprolol (1.25 mg daily)
2. Placebo

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
The change from baseline in plasma BNP measurements

Key secondary outcome(s))
Not provided at time of registration

Completion date
19/12/2006

Eligibility

Key inclusion criteria
A total of 40 patients with evidence or history of clinical heart failure, ejection fraction of >45% and raised plasma BNP levels.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. History of asthma / COPD
2. Hypotension, patients with significant bradycardia
3. BMI>30
4. Intolerant of beta-blockers, patients with constrictive pericarditis, with severe peripheral vascular disease, patients having suffered myocardial infarction within 3 months prior to enrolment
5. Pregnant women
6. Use of any investigational drug within 2 weeks of enrolment
7. Any recent changes in cardiac medications

Date of first enrolment
01/09/2005

Date of final enrolment
19/12/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Manchester University Hospitals NHS Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
South Manchester University Hospitals NHS Trust

Funder Name
South Manchester University Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration