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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

Registration date
29/09/2006

Overall study status
Completed

Last Edited
28/10/2016

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

Contact name
Dr Nicholas Brooks

Contact details
South Manchester University Hospitals NHS Trust
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT
+44 (0)161 291 2751/ 2752/ 2743
nicholas.brooks@smtr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
The change from baseline in plasma BNP measurements

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

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

Age group
Adult

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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