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A physiological evaluation of non invasive ventilation (NIV) during exercise in patients with chronic heart failure (CHF).

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/03/2016	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436130405

Study information

Scientific Title
A physiological evaluation of non invasive ventilation (NIV) during exercise in patients with chronic heart failure (CHF).

Study objectives
To examine the effects of non invasive ventilation (NIV) in patients with CHF on exercise capacity. This study aims to examine the effect of NIV on exercise capacity in patients with CHF, comparing NIV, sham NIV and no ventilatory support.

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

Health condition(s) or problem(s) studied
Chronic heart failure (CHF)

Interventions
Randomised controlled trial to examine the effect of NIV on exercise capacity in patients with CHF, comparing NIV, sham NIV and no ventilatory support.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Peak oxygen consumption in order to establish the effect of NIV on exercise capacity in patients with CHF.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2002

Completion date
01/02/2004

Eligibility

Key inclusion criteria
Patients with New York Heart Association (NYHA) class 2 to 4 CHF

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2002

Date of final enrolment
01/02/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leeds Teaching Hospitals NHS Trust
Respiratory Department
Gledhow Wing
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LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust

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