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Auto-titrating continuous positive airway pressure in patients with chronic heart failure and obstructive sleep apnoea

Submission date 23/04/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/11/2006	**Overall study status** Completed	
Last Edited 14/11/2022	**Condition category** Circulatory System	

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
PG/02/131/14612

Study information

Scientific Title
Auto-titrating continuous positive airway pressure in patients with chronic heart failure and obstructive sleep apnoea

Study objectives
Auto-titrating Continuous Positive Airway Pressure (CPAP) improves subjective and objective measures of Chronic Heart Failure (CHF) severity in patients with CHF and Obstructive Sleep Apnoea (OSA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial was approved by the Lothian Regional Ethics Committee (ref: LREC/2002/4/25) in 2002.

Study design
Randomised double-blind placebo-controlled crossover 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 and obstructive sleep apnoea

Interventions
Auto-titrating CPAP versus sham CPAP.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes in peak maximal oxygen uptake (VO2) and six-minute walk distance.

Secondary outcome measures

Changes in:
1. LVEF
2. Minute ventilation versus carbon dioxide production (VE/VCO2) slope
3. Plasma neurohormonal makers
4. Quality of life

Overall study start date
01/07/2002

Completion date
01/04/2005

Eligibility

Key inclusion criteria
1. Stable symptomatic CHF (Left Ventricular Ejection Fraction [LVEF] less than 45%)
2. On optimal medical therapy with obstructive sleep apnoea (Apnea-Hypopnea Index [AHI] more than or equal to 15)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Total final enrolment
26

Key exclusion criteria
1. Acute coronary syndrome less than 3/12
2. Primary valvular heart disease
3. Sustained ventricular arrhythmias
4. Stroke with residual neurological deficit

Date of first enrolment
01/07/2002

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Cardiovascular Science
Edinburgh
United Kingdom
EH16 4SB

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Old College
South Bridge
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Scotland
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Sponsor type
University/education

Website
http://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK) (ref: PG/02/131/14612, PG/02/078/14122)

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2007		Yes	No