

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/11/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Changes in:

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

Scotland

Study participating centre

Centre for Cardiovascular Science

Edinburgh

United Kingdom

EH16 4SB

Sponsor information

Organisation

University of Edinburgh (UK)

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Charity

Funder Name

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

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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