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Multicentre trial of continuous Positive Airway Pressure for chronic therapy of heart failure

Submission date	Recruitment status	[_] Prospectively registered
17/06/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/04/2010	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
UCT-14909

Study information

Scientific Title

Acronym
CANPAP

Study objectives
To test the effect of continuous positive airway pressure (CPAP) on the combined rate of death and cardiac transplantation in congestive heart failure (CHF) patients with central sleep apnoea (CSA)

Ethics approval required
Old ethics approval format

Ethics approval(s)
The research ethics board of each institution approved the protocol:
1. Canada: University of Calgary, University of Alberta, University of Western Ontario, McGill University, Laval University, University of Toronto (site A: Toronto General Hospital of the University Health Network, site B: St. Michael's Hospital), University of British Columbia, University of Manitoba
2. Germany: University of Regensburg

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Congestive heart failure

Interventions
Control group: Standard drug therapy for CHF
Experimental group: CPAP in addition to standard drug therapy

Both groups will be closely followed for an average of approximately 2.5 years. Assessments at one, three and six months, two years and end of trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Combined death-heart transplantation rate

Secondary outcome measures
1. Changes in resting LVEF
2. Left ventricular end diastolic volume (LVEDV), left ventricular end systolic volume (LVESV)
3. Distance walked on a six minute walk test
4. New York Heart Association (NYHA) functional class
5. Quality of life
6. Sleep quality
7. Frequency of apnoeas and hypopnoeas
8. Mean and minimal saturation of oxygen (SaO2) from baseline
9. Number of admissions and total days spent in hospital over the entire trial period

Overall study start date
01/12/1998

Completion date
31/05/2004

Eligibility

Key inclusion criteria
1. Male and females between the age of 18 and 79 with history of at least one clinical episode of CHF due to ischaemic heart failure
2. Left ventricular (LV) systolic dysfunction as evidenced by a left ventricular ejection fraction (LVEF) at rest determined by equilibrium radionuclide angiography of less than 40% while on optimal drug therapy at the time of recruitment
3. New York Heart Association (NYHA) functional class two to four
4. Stable condition and stable optimal cardiac medications for at least one month prior to entry
5. Presence of central sleep apnoea defined as more than or equal to 15 apnoeas and hypopneas per hour of sleep of which more than 50% must be central in nature
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
408

Key exclusion criteria
1. History of unstable angina, cardiac surgery and/or documented myocardial infarction less than three months prior to entry into the study
2. Acceptance for cardiac transplantation
3. Sleep apnea which is predominantly (i.e. more than or equal to 50%) obstructive in nature
4. Concurrent disease that would markedly limit life expectancy (e.g. lung cancer)
5. Pregnancy

Date of first enrolment
01/12/1998

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
Canada

Study participating centre
Toronto General Hospital-UHN
Toronto, Ontario
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M5G 2C4

Sponsor information

Organisation
University Health Network (Toronto) (Canada)

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Sponsor type
University/education

Website
http://www.uhn.ca

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: UCT-14909)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2001		Yes	No
Results article	results	10/11/2005		Yes	No
Results article	results	26/06/2007		Yes	No
Results article	results	01/01/2009		Yes	No
Results article	results	01/03/2010		Yes	No