

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

Submission date 17/06/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 17/06/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/04/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr T Douglas Bradley

Contact details
Toronto General Hospital-UHN
EC 6-248
200 Elizabeth Street
Toronto, Ontario
Canada
M5G 2C4
+1 416 340 4719
douglas.bradley@utoronto.ca

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Combined death-heart transplantation rate

Key secondary outcome(s)

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

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 hypopnoeas per hour of sleep of which more than 50% must be central in nature
6. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Canada

M5G 2C4

Sponsor information

Organisation

University Health Network (Toronto) (Canada)

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

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?
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
Protocol article	protocol	01/06/2001		Yes	No