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Multicentre randomised placebo-controlled trial of nocturnal oxygen therapy in chronic obstructive pulmonary disease

Submission date 19/10/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 21/12/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/12/2007	**Condition category** Respiratory	[_] 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

Protocol serial number
MOP-36329

Study information

Scientific Title

Acronym
CANOX trial

Study objectives
Long-term oxygen therapy (LTOT) is the only component of the management of chronic obstructive pulmonary disease (COPD) that improves survival in patients with severe daytime hypoxemia. In Canada, LTOT is usually provided by a stationary oxygen concentrator and is recommended to be used for at least 15 - 18 hours a day. Several studies have demonstrated a deterioration in arterial blood gas pressures and oxygen saturation during sleep in patients with COPD. Sleep-related oxygen desaturation often occurs in patients not qualifying for LTOT. The suggestion has been made that the natural progression of COPD to its end stages of chronic pulmonary hypertension, severe hypoxemia, right heart failure, and death is dependent upon the severity of desaturation occurring during sleep. This is an attractive hypothesis and is supported by the fact that hypoxemic episodes during sleep are accompanied by substantial increases in pulmonary arterial pressure and often by important cardiac arrhythmias. Supplemental nocturnal oxygen alleviates both the acute increases in pulmonary arterial pressure and the cardiac arrhythmias.

It has been suggested that, over the long run, nocturnal oxygen therapy (N-O2) may halt the progression of long-standing cor pulmonale and prolong survival. Probably due to the fact that the recommendations of scientific societies regarding the indications for and use of N-O2 in COPD not qualifying for conventional LTOT are presently imprecise, a number of patients are currently treated with N-O2 although the beneficial effects of this therapy have not been confirmed.

Hypothesis:
In patients with Chronic Obstructive Pulmonary Disease (COPD) not qualifying for Long Term Oxygen Therapy (LTOT) but who present significant nocturnal arterial oxygen desaturation, nocturnal oxygen therapy provided for a period of 3 years is effective in decreasing mortality or delaying the requirement for LTOT, and is cost-effective and favourably compares to other medical interventions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending as of 20/10/2006.

Primary study design
Interventional

Study design
A 3-year, multicentre, placebo-controlled, randomised trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
1. Nocturnal oxygen therapy group: N-O2 will be delivered overnight to allow the oxygen saturation to be greater than 90%
2. Placebo: the patients allocated in the control group will receive room air delivered by sham concentrator

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nocturnal oxygen therapy

Primary outcome(s)
The primary outcomes of this trial are mortality from all cause or requirement for LTOT (composite outcome).

Key secondary outcome(s)
1. Quality of life and utility measures
2. Costs from a societal perspective
3. Compliance with oxygen therapy

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of COPD supported by an history of past or current smoking and obstructive disease with forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) less than 60%
2. Presence of mild-to-moderate daytime hypoxemia with a daytime partial pressure of oxygen in arterial blood (paO2) in the range of 56 - 69 mmHg
3. Patients fulfilling our definition of nocturnal oxygen desaturation: greater than or equal to 30% of the recording time with transcutaneous arterial oxygen saturation less than 90% on two consecutive recordings

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Patients fulfilling the usual criteria for continuous oxygen therapy (CONT-O2) at study entry:
1.1. PaO2 less than or equal to 55 mmHg, or
1.2. PaO2 less than or equal to 59 mmHg with clinical evidence of at least one of the following:
1.2.1. Pulmonary hypertension
1.2.2. Right ventricular hypertrophy
1.2.3. Cor pulmonale
1.2.4. Haematocrit greater than or equal to 55%
2. Patients with sleep apnea (defined by an apnoea/hypopnoea index of greater than or equal to 15 events/hour
3. Patients currently on nocturnal oxygen therapy (N-O2)
4. Patients with known left heart or congenital heart diseases, interstitial lung diseases, bronchiectasis as the main cause of their obstructive disease, lung carcinoma or other severe diseases that could influence survival (hepatic cirrhosis and chronic renal failure)

Date of first enrolment
01/09/2008

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Canada

Study participating centre
Centre de Pneumologie
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Canada
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Sponsor information

Organisation
Laval University (Canada)

ROR
https://ror.org/04sjchr03

Funder(s)

Funder type

Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MOP-36329)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration