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The Canadian Nocturnal Oxygen (CANOX) trial

Submission date 16/09/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2009	**Overall study status** Completed	
Last Edited 23/04/2021	**Condition category** Respiratory	

Plain English summary of protocol
06/06/2019: This record contains out of date information and will not be updated further. Please see https://clinicaltrials.gov/ct2/show/NCT01044628 for the most up to date trial record.

Plain English summary 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
NCT01044628

Secondary identifying numbers

MCT-99512

Study information

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

Acronym
CANOX, INOX

Study objectives
In patients with chronic obstructive pulmonary disease (COPD) not qualifying for long-term oxygenotherapy (LTOT) but who present significant nocturnal arterial oxygen desaturation, nocturnal oxygen (N-O2) provided for a period of 3 years is effective in decreasing mortality or delaying the requirement for LTOT, and is cost-effective and favorably compares to other medical interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Comité d'éthique de la recherche de l'Institut universitaire de cardiologie et de pneumologie de Québec [Hôpital Laval]) pending approval; meeting planned for 03/11/2009

Study design
Multicentre placebo-controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions

Nocturnal oxygen therapy (N-O2 study group): oxygen delivered overnight to allow the oxygen saturation to be greater than 90%
Placebo (control group): room air delivered by defective concentrator

The comparison will be double blind. COPD patients will be randomly assigned to 3 years of treatment with either home N-O2 or sham therapy with ambient air. Each patient will be followed-up for this period of 3 years, with regular visits (every 4 months) until one of the following events: the patient is prescribed LTOT or the patient dies.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Mortality from all cause
2. Requirement for LTOT (composite outcome)

The usual socio-demographic and clinical characteristics will be obtained at baseline. Spirometry will be performed according to the American Thoracic Society requirements, lung volumes measurement by plethysmography, and carbon monoxide diffusion capacity measurement by the single-breath method (all measured at baseline, 12, 24 and 36 months). All arterial blood gases will be measured while breathing at room air (measured at baseline and every 4 months until 36 months). In case of death, the date at which the primary outcome is reached will be obtained directly from chart review, contact with the treating physician or on the basis of interviews with surviving relatives during the protocol-based home visits or telephone interviews.

Secondary outcome measures
1. Quality of life and utility measures, measured at baseline, 12 months, 24 months and 36 months
2. Costs from a societal perspective, measured through telephone contacts with patients every two months
3. Compliance with oxygen therapy, measured at 4, 8, 12, 16, 20, 24, 28, 32 and 36 months

Overall study start date
01/03/2010

Completion date
01/03/2014

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of COPD supported by a history of past or current smoking and obstructive disease: forced expiratory volume in one second (FEV1) less than 50% predicted, FEV1/forced vital capacity (FVC) less than 70% and a total lung capacity by body plethysmography greater than 80% predicted
2. Stable COPD at study entry for at least 6 weeks before enrolment in the trial, as demonstrated by:

2.1. No acute exacerbation
2.2. No change in medications
3. Non-smoking patients for at least 6 months before enrolment in the trial
4. Mild-to-moderate daytime hypoxaemia with a resting partial pressure of oxygen in arterial blood (PaO2) (room air) in the range of 56 - 69 mmHg
5. Patients fulfilling the current definition of nocturnal oxygen desaturation, i.e., greater than or equal to 30% of the recording time with transcutaneous arterial oxygen saturation less than 90% on at least one of two consecutive recordings
6. Ability to give informed consent
7. Men and women aged over 40 years of age

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
630

Total final enrolment
243

Key exclusion criteria
1. Patients with severe hypoxaemia fulfilling the usual criteria for continuous oxygen (CONT-O2) at study entry: PaO2 less than or equal to 55 mmHg or PaO2 less than or equal to 59 mmHg with clinical evidence of at least one of the following:
1.1. Pulmonary hypertension
1.2. Right ventricular hypertrophy
1.3. Cor pulmonale
1.4. Haematocrit greater than or equal to 55%
2. Patients with proven sleep apnoea (defined by an apnoea/hypopnoea index of greater than or equal to 15 events/hour) or suspected sleep apnoea on oximetry tracings
3. Patients currently using nocturnal oxygen therapy (NO2)
4. Patients with known left heart or congenital heart diseases, interstitial lung diseases, bronchiectasis as the main cause of obstructive disease, lung carcinoma, severe obesity (body mass index greater than or equal to 40 kg/m^2), or any other disease that could influence survival

Date of first enrolment
01/03/2010

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
Canada

Study participating centre
Centre de recherche de lInstitut de cardiologie et de pneumologie de Québec (CRICPQ)
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Sponsor information

Organisation
Laval Hospital (Hôpital Laval) (Canada)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.hopitallaval.qc.ca/

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) (ref: MCT-99512)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	09/01/2017		Yes	No
Results article		17/09/2020	23/04/2021	Yes	No