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Effects of proton pump inhibitor treatment on apnea severity in patients with laryngopharyngeal reflux and obstructive sleep apnea

Submission date 25/10/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/01/2007	**Overall study status** Completed	
Last Edited 05/01/2007	**Condition category** Musculoskeletal Diseases	

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
N/A

Study information

Scientific Title

Study objectives
In patients with mild to moderate Obstructive Sleep Apnea (OSA) and endoscopic evidence of laryngeal inflammation, proton pump inhibitor treatment will lead to an improvement in apnea severity and apnea-related symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill University Health Centre Research Ethics Board (Study No. BMA 05-018), approved January 24, 2006.

Study design
Randomised, controlled trial, single-blinded: drug versus no-drug.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Obstructive Sleep Apnea

Interventions
Six month treatment with Lansoprazole 30 mg orally twice a day (BID) or no drug.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Lansoprazole

Primary outcome measure
Change in apnea-hypopnea index from baseline to six months.

Secondary outcome measures
1. Laryngoscopic Reflux Finding Score
2. Laryngeal air pressure pulse sensory threshold
3. Reflux Symptom Index
4. Epworth Sleepiness Score
5. Quebec Sleep Apnea Quality of Life Index
6. Functional Outcomes of Sleep instrument

All at baseline, four and six months; also Polysomnographic variables other than apnea-hypopnea Index at baseline and six months.

Overall study start date
01/11/2006

Completion date
31/10/2007

Eligibility

Key inclusion criteria
1. Adults 20 to 70 years with untreated obstructive sleep apnea, non-smoking
2. Epworth sleepiness score less than 15
3. Apnea-hypopnea index of 15 to 60 events per hour, with Non-Rapid Eye Movement Apnea Hypopnea Index (NREM AHI) more than 10, nadir Saturation of Oxygen in arterial blood (SaO2) more than or equal to 80% at overnight polysomnography
4. Reflux Finding Score more than 7 on laryngoscopy

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
44 (22 per group)

Key exclusion criteria
1. Any prior treatment for OSA
2. Current or past proton pump inhibitor therapy, current inhaled or systemic corticosteroid, or systemic immunosuppressive treatment
3. Active cardiovascular disease (uncontrolled hypertension, unstable angina, myocardial infarction within the preceding six months, congestive heart failure)

4. Epworth Sleepiness Score more than 15 or employment in a safety critical position regardless of Epworth Score
5. History of a bleeding disorder
6. Otolaryngologic conditions including glottic or subglottic stenosis, cancer of the larynx, previous radiotherapy, upper airway surgery other than remote tonsillectomy, or major craniofacial malformation

Date of first enrolment
01/11/2006

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
Canada

Study participating centre
McGill University Health Centre
Montreal, Quebec
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Sponsor information

Organisation
McGill University Health Centre Research Institute (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.muhc.ca/research

ROR

https://ror.org/04cpxjv19

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Operating funds provided by the Sponsor: MUHC Research Institute (Canada)

Funder Name
Study drug, but no operating or other funds provided by Abbott Laboratories (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