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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Richard John Kimoff

**Contact details**
McGill University Health Centre
Room L4.08
687 Pine Ave W
Montreal, Quebec
Canada
H3A 1A1
+1 514-934-1934, ext. 36117
john.kimoff@muhc.mcgill.ca

## 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
Canada
H3A 1A1

## Sponsor information

### Organisation
McGill University Health Centre Research Institute (Canada)

### Sponsor details
1650 Cedar Ave
Room A6.141
Montreal, Quebec
Canada
H3G 1A4
+1 514-934-1934 ext. 44580
lynn.derycapes@muhc.mcgill.ca

### 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