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Inspiratory airflow limitation during sleep: its relationship to functional complaints

Submission date 08/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 25/09/2006	**Overall study status** Completed	
Last Edited 25/09/2006	**Condition category** Respiratory	

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
Stony Brook Research Foundation #1051610

Study information

Scientific Title

Study objectives
Patients with Upper Airway Resistance Syndrome (UARS) who are randomised to therapeutic Continuous Positive Airway Pressure (CPAP) will demonstrate reduced pain, fatigue, daytime sleepiness, headache, gastrointestinal discomfort, hyperarousal, and metabolic risk factors after three weeks of treatment compared to UARS patients randomised to sham CPAP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stony Brook University Internal Review Board (reference number: 2006-6309), approved on the 28th August 2006.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Upper airway resistance syndrome

Interventions
Following baseline assessment, participants will be randomised to the experimental condition: therapeutic CPAP (n=10) or sham CPAP (n=10). A permuted blocking procedure will be used for the randomisation assignments using two block sizes (four and six). Allocation concealment from research assistants conducting outcome assessments will be done to minimise assignment bias and to attempt to maintain blinding of assessors. The study coordinator, who will not have direct contact with participants, will be responsible for implementing randomisation.

Per instruction from the study coordinator, one member of the research team will prepare the CPAP device as therapeutic or sham and provide it to another member of the team (blinded) who will interface with the patients to train them in use of the CPAP and answer questions or coach compliance during the trial. Patients will receive treatment for three weeks and then

return for post-treatment assessment. The research assistant responsible for gathering pre- and post-treatment data will also be blinded to experimental condition.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Fatigue
2. Daytime sleepiness
3. Sleep quality

Secondary outcome measures
1. Pain
2. Headache
3. Gastrointestinal discomfort
4. Metabolic risk factors
5. Hyperarousal

Overall study start date
11/09/2006

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Physician-confirmed diagnosis of UARS
2. Aged between 21 years or over and 65 years or under
3. Able to speak and read English
4. Ability to tolerate only one caffeinated beverage in the morning

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Currently taking an opiate, benzodiazepine, sedative, hypnotic, stimulant, or sleeping medication

2. Currently being treated with a lipid lowering or Blood Pressure (BP) medication
3. Diagnosis and/or treatment for sleep apnea, narcolepsy, or periodic limb movement disorder
4. Diagnosis of diabetes, coronary artery disease, Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), stroke, or seizures
5. Body Mass Index (BMI) over 32 (no lower limit)
6. Evidence of overt alcohol or other substance abuse
7. History of allergy to lidocaine or similar local anesthestics
8. Presence of an extreme gag reflex
9. Difficulty breathing through nose
10. Smoking
11. Waking after 10:00 a.m. and going to bed after 12:00 a.m

Date of first enrolment
11/09/2006

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Psychiatry & Behavioral Science
New York
United States of America
11794-8790

Sponsor information

Organisation
Respironics, Inc (USA)

Sponsor details
1001 Murry Ridge Lane
Murrysville
Pennsylvania
United States of America
15668-8550

Sponsor type
Industry

Website

http://www.respironics.com

ROR
https://ror.org/03kw6wr76

Funder(s)

Funder type
Industry

Funder Name
Respironics, Inc. (USA)

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