

Inspiratory airflow limitation during sleep: its relationship to functional complaints

Submission date 08/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/09/2006	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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 anesthetics
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