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TransNasal Insufflation for obstructive sleep apnoea (OSA)

Submission date	Recruitment status	[ ] Prospectively registered
27/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/04/2008	Nervous System Diseases	[ ] 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

Protocol serial number
MR-0739-TNI-SS

Study information

Scientific Title

Acronym
TNI

Study objectives
H1: Transnasal insufflation (TNI) will reduce significantly the apnoea/hypopnoea index (AHI) and the arousal index (ArI) in newly diagnosed patients with obstructive sleep apnoea (OSA). Apnoeas and hypopnoeas will be examined separately in post hoc analyses. The first hypothesis will be assessed by comparing the AHI at each overnight visit (diagnostic and TNI) employing a paired t-test. If significant findings are obtained, paired t-tests will be employed to examine separately apnoeas and hypopnoeas.

H2: Patients will rate the comfort of TNI and their confidence to use the device nightly. Hypothesis two will be assessed by collating comfort ratings and examining them visually. These ratings will also be correlated with adherence data.

H3: Adherence to TNI will be better than historical averages of positive airway pressure (PAP) adherence (e.g., four hours per night). Hypothesis three will be assessed by collating adherence monitoring and comparing these data to historical controls on PAP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Allendale Investigational Review Board on the 6th December 2007.

Primary study design
Interventional

Study design
Single site, efficacy, proof of concept trial.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
This is a within-subjects study of the efficacy of TNI at reducing sleep disordered breathing (SDB) in participants with newly diagnosed sleep apnoea. Thirty participants with diagnosed OSA will be recruited after a standard diagnostic polysomnographic (PSG) study. For the purposes of this study, if a split night study is completed and PAP titration is initiated, subjects will still be considered naive.

Individuals who agree to participate in the study will be provided TNI during an overnight PSG. TNI will be set at 22 lpm for all participants. PSG acquisition will follow standard guidelines for diagnosis, but TNI will be operative during the TNI PSG. Participants will be questioned as to their perceived comfort and ease of therapy the morning after the TNI PSG. Participants will then be sent home with the device. Contact will be made at one week to assess comfort, ease of use and adherence. The final assessment of comfort, ease of use and adherence will occur between 14 - 30 days with TNI. At the termination of the study the patients will undergo a

second standard PSG with TNI in place. TNI will be set at 22 lpm for all participants. PSG acquisition will follow standard guidelines for diagnosis, but TNI will be operative during the TNI PSG.

Participants will then be referred for standard clinical treatment as clinically indicated by their original diagnostic PSG. Those participants who elect to receive PAP treatment will be asked if they are willing to fill out a similar comfort questionnaire and to have adherence monitored 14 - 30 days after the start of PAP therapy. Willing participants will receive one additional assessment phone call after 14 - 30 days. Their responses to the questions will be recorded for later analysis.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
There are four primary dependent variables for this study:
1. AHI
2. Arousal index
3. Treatment adherence, and
4. Perception of treatment

AHI and arousal index will be monitored with overnight PSG and comparisons will be made between the baseline, diagnostic PSG and the two PSGs with TNI (initiation and termination). TNI adherence will be monitored objectively by equipping the TNI device with an objective monitor of use time. This will be accomplished using a small infra-red sensor that will be mounted to the cannula and worn by the patient when TNI is operating. The signal will be sent to a Palm Pilot where the objective compliance data will be recorded and downloaded. Adherence is a complicated variable and, if not normally distributed, may be categorised based upon accepted definitions. In such a case, these categories would be employed as dependent measures of this outcome variable (e.g., percentage patients averaging four hours/night and six hours/night). All participants will be informed that adherence will be monitored to reduce deception. Adherence will be compared to historical controls with PAP therapy. Comfort ratings will be obtained along with patient preference during the course of the study, including with PAP on those participants agreeing to be followed with traditional treatment. Comfort ratings will also be correlated with adherence as a validation of the comfort scale. We will also incorporate measures of self-efficacy for OSA treatment. Self-efficacy has been a strong predictor of long-term adherence and will provide insight into one potential mediator of adherence across conditions.

Key secondary outcome(s)
No secondary outcome measures

Completion date
12/01/2008

Eligibility

Key inclusion criteria

1. Aged 21 - 65 years, either sex
2. Diagnosis of OSA with a baseline AHI between 15 and 50 events/hour of sleep
3. Able and willing to provide written informed consent
4. English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation in another interventional research study within the last 30 days
2. Major controlled or uncontrolled medical condition such as congestive heart failure, neuromuscular disease, renal failure etc.
3. Prior PAP use or treatment for OSA, excluding split-night PAP exposure
4. Chronic respiratory failure or insufficiency with suspected or known neuromuscular disease, moderate or severe chronic obstructive pulmonary disease (COPD), or any condition with an elevation of arterial carbon dioxide levels while awake (PaCO2 greater than or equal to 55 mmHg)
5. Presence of untreated, non-OSA related sleep disorders, e.g., moderate to severe restless legs (Periodic Limb Movement Index [PLMI] greater than or equal to 10) or insomnia
6. Body mass index (BMI) greater than 40 kg/m^2. Most subjects will have a BMI less than or equal to 35 kg/m^2 but we will include a small subset of subjects with a BMI greater than 35 kg /m^2 but less than or equal to 40 kg/m^2.
7. Severe sleepiness (automobile accident or near accident in the last 12 months due to sleepiness)
8. Severe oxygen desaturation on the polysomnography (PSG) (oxygen saturation [Sa02] less than 70% for 10% of the diagnostic PSG study)
9. Surgery of the upper airway, nose, sinus or middle ear within the past 90 days
10. Currently using supplemental oxygen
11. Regular use of sleeping pills or stimulants
12. Currently working night shift or rotating day/night shift

There will be no exclusion based on gender, race or ethnicity.

Date of first enrolment
12/01/2007

Date of final enrolment
12/01/2008

Locations

Countries of recruitment
United States of America

Study participating centre
1505 Commonwealth Ave
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United States of America
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Sponsor information

Organisation
Respironics, Inc. (USA)

ROR
https://ror.org/03kw6wr76

Funder(s)

Funder type
Industry

Funder Name
Respironics, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration