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Treatment by uninterrupted positive airway pressure by nasal route - Evaluation of REMstar® Auto with C-Flex in clinical practice

Submission date
29/09/2008

Recruitment status
No longer recruiting

Registration date
20/11/2008

Overall study status
Completed

Last Edited
20/11/2008

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N/A

Study information

Scientific Title

Study objectives
REMstar® Auto with C-FLEX is as effective at reducing the apnoea-hypopnoea index (AHI) in sleep apnoea/ hypopnoea patients as continuous positive airway pressure over 30 days when used in the home environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee for Protection of Human Subjects, Poitou-Charentes (Comite Consultatif de Protection des Personnes dans la Recherche, Biomedicale de la region Poitou-Charentes), approved on 20/10/ 2005 (ref: 05.09.17)

Study design
Randomised crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact etails below to request a copy of the information sheet

Health condition(s) or problem(s) studied
Sleep apnoea/ hypopnoea syndrome

Interventions
Participants were randomly allocated to the following two arms:

Arm 1: REMstar® Auto with C-FLEX over 30 days
Arm 2: Continuous positive airway pressure over 30 days

The intervention was followed by a 7-day washout period, and then the participants were crossed over to 30 days on alternate arm of study.

Intervention Type

Other

Phase
Phase IV

Primary outcome measure
1. To determine if the REMstar® Auto in C-Flex mode is as effective as constant positive airway pressure on reducing the AHI of sleep apnoea/ hypopnea patients when used in the home environment. This will be assessed by data obtained during polygraph recording via the Stardust® device at the beginning and end of each period (30 days, 7-day washout then 30 days on alternate arm of study) and between each mode of use. This relates primarily to the following:
a. AHI index
b. Sa02 night (minimum, maximum and Sa02 95)

2. Data from the REMstar® device at the beginning and end of each period and between each mode of use. This relates primarily to the following:
a. Maximum pressure
b. Minimum pressure
c. Average pressure
d. Average number of hours use on nights used
e. AHI index

Secondary outcome measures
1. To compare the clinical benefits and preference of patients between the REMstar® Auto in C-Flex mode versus conventional fixed pressure. This will be assessed at the beginning and end of each period and between each mode of use.
2. Quality of life and daytime alertness will be assessed by the Functional Outcome of Sleep Questionnaire (FOSQ) and the Epworth Sleepiness Questionnaire (ESS). Timepoints: Baseline (before first mode of use), after first mode of use is completed and after the second mode of use is completed.
3. A visual analogue scale will be completed by the participants at the end of each treatment period to assess daytime alertness

Overall study start date
06/10/2005

Completion date
13/03/2008

Eligibility

Key inclusion criteria
1. Male adults >18
2. Index of apnoea/ hypopnoeas >30/hour
3. Able to provide written consent

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
20

Key exclusion criteria
1. Past experience of treatment with positive airway pressure or non invasive ventilation
2. Participants who require 2 levels of pressure for nocturnal alveolar hypoventilation linked to a co-morbidity (obesity, hypoventilation, chronic obstructive pulmonary disease [COPD]) of sleep aponea/ hypopnoea syndrome
3. Participants that have undergone surgery for the treatment of sleep apnoea/ hypopnoea syndrome, snore or tumour in the last 6 months or after their polysomnography (PSG) diagnosis
4. Tracheostomy
5. Respiratory infection, sinusitis or internal ear infection
6. Dermatitis or other facial lesions preventing the application of a mask
7. Unable to give written informed consent
8. Participants unwilling to volunteer
9. Unstable medication
10. Participants presenting with clinically significant COPD or unstable cardiac insufficiency
11. People benefiting from a reinforced protection will not be included in this study. This refers to subjects protected by law, persons accepted in a health or social establishment, private individuals of freedom by a court or administrative order, ill in urgent situation, and persons hospitalised without consent.
12. Participants should not have participated in a trial in the 3 months preceding or following the study

Date of first enrolment
06/10/2005

Date of final enrolment
13/03/2008

Locations

Countries of recruitment
France

Study participating centre
Service de Pneumologie
Poitiers
France
86021

Sponsor information

Organisation
Respironics International (France)

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Sponsor type
Industry

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ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International (France)

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