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P-Flex Validation in patients with documented Obstructive Sleep Apnoea (OSA)

Submission date
02/10/2012

Recruitment status
No longer recruiting

Registration date
08/10/2012

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study on 30 subjects with documented Obstructive Sleep Apnoea (OSA). Obstructive sleep apnoea is the most common type of sleep apnoea and is caused by obstruction of the upper airway. It is characterized by repetitive pauses in breathing during sleep, despite the effort to breathe. Continuous Positive Airway Pressure (CPAP) is the first line medical therapy for treatment of OSA. A CPAP device is used when the subject is asleep and increases pressure in the throat to stop the airways collapsing when the subject breathes in.
In this study subjects will use the PR1 REMstar Auto with P-Flex (a CPAP device) to treat their sleep apnoea. Our goal is to find out if the PR1 REMstar Auto with P-Flex will reduce the subjects Apnoea Hypopnoea Index to an acceptable level. We will also look at other features of the subjects sleep report (polysomnography), daytime sleepiness, how often the subjects uses the device, how comfortable the device is to use and the pressure levels delivered by the device.

Who can participate?
Men and Women with documented Obstructive Sleep Apnoea, confirmed by polysomnography who are aged >21

What does the study involve?
Suitable subjects who have had a recent sleep study (polysomnography) will be invited to take part in this study. Subjects will be required to attend the sleep clinic three times throughout the study at set intervals. At the first visit subjects will be required to undergo a medical examination (to collect age, gender, height, weight, BMI, waist and neck measurements), complete a questionnaire and receive training on the device and mask to be used in the study. At the second and third visit the medical examination will be repeated (weight, BMI, waist and neck measurements), subjects will need to complete two questionnaires and the data recorded on the device will be retrieved. In addition at the third visit subjects will be required to undergo an overnight sleep study at the sleep centre using the study device.
At the end of the study we will look at all of the data collected to find out if the PR1 REMstar Auto with P-Flex device treated the subjects obstructive sleep apnoea to an acceptable level.

What are the possible benefits and risks of participating?
We believe that PR1 REMstar Auto with P-Flex reduces the Apnoea Hypopnoea Index, to an

acceptable level in patients with measured documented OSA. Furthermore PR1 REMstar Auto with P-Flex changes other indices of the polysomnography study in an acceptable manner in patients with documented OSA. It is hoped that PR1 REMstar Auto with P-Flex reduces daytime sleepiness to an acceptable level and that minimally acceptable compliance levels can be achieved by patients with documented OSA who use the PR1 REMstar Auto with P-Flex. We also believe that the PR1 REMstar Auto with P-Flex is comfortable and easy to use.
We believe that the risks of providing positive airway pressure therapy with the PR1 REMstar Auto with P-Flex are no greater than the risks encountered with other assisted PAP devices. We believe that no significant risks will be posed to the subjects participating in this protocol, as the study is non invasive, use of the devices will be monitored by trained clinical staff in the sleep laboratory and the PAP equipment has been tested to ensure safety. The patient can also easily remove their interface device should it become uncomfortable or make breathing difficult. Rarely, there may be skin irritation in response to the substance used to attach some of the electrodes. Other potential side effects of PAP therapy may include: ear discomfort, conjunctivitis, skin abrasions due to non-invasive interfaces and gastric distension, all of which are quite uncommon. Thus, we believe that the risks and discomfort associated with participation in this study are minimal.

Where is the study run from?
Clinique La Louviere, 69 rue de la Louviere, 59800 Lille, France

When is the study starting and how long is it expected to run?
It is anticipated that recruitment will start in October 2012. Subjects will be enrolled for about 84 days.

Who is funding the study?
Philips Home Healthcare Solutions

Who is the main contact?
Dr Thibaut Gentina
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Contact information

Type(s)
Scientific

Contact name
Dr Thibaut Gentina

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Additional identifiers

Protocol serial number
EAME11PFlex01

Study information

Scientific Title
P-Flex Validation in patients with documented Obstructive Sleep Apnoea (OSA): an observational study

Study objectives
The PR1 REMstar Auto with P-Flex will reduce the Apnoea Hypopnoea Index (AHI) in patients with documented OSA (Obstructive Sleep Apnoea).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for the Protection of Persons Ile de France VIII (Comite de Protection des Personnes Ile de France VIII), 11/09/2011, Ethics Reference Number: CPP: 12 09 85

Primary study design
Observational

Study design
Observational Study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructive Sleep Apnoea

Interventions
Visit 1 (Baseline)
1. Inclusion/Exclusion
2. Demographic Data (age, gender, height, weight, BMI, waist and neck circumference)
3. Polysomnography (PSG) data
4. Epworth Sleepiness Scale (ESS)
5. Educational session on the use of the P-Flex device
6. Mask fitting
7. Set date for Visit 2

Visit 2 (day 15 plus or minus 5 days)
1. Demographic Data (weight, BMI, waist and neck circumference)
2. ESS questionnaire
3. Comfort and Ease of Use questionnaire (5 point likert scale)
4. Compliance and Therapy data downloaded from device SD card
5. Set date for Visit 3

Visit 3 (84 days plus or minus 14 days)
1. Demographic Data (weight, BMI, waist and neck circumference)
2. ESS questionnaire
3. Comfort and ease of Use questionnaire (5 point likert scale)
4. Compliance and Therapy data downloaded from device SD card
5. Overnight PSG while using PR1 REMstar Auto with P-Flex device

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The PR1 REMstar Auto with P-Flex reduces the Apnoea Hypopnoea Index (AHI) to less than 15 in patients with documented OSA, when measured using full polysomnography

Key secondary outcome(s)
1. The PR1 REMstar Auto with P-Flex changes other indices of the polysomnography study in an acceptable manner (SpO2 ,total sleep time, Sleep efficiency and arousals)
2. The PR1 REMstar Auto with P-Flex reduces the Epworth Sleepiness Scale (ESS) to less than 11 in patients with documented OSA
3. Patients demonstrate a compliance of greater than or equal to 3 hours per 24 hrs when using the PR1 REMstar Auto with P-Flex
4. An average score of greater than or equal to 3 on the comfort and ease of use questionnaire
5. There will be an average pressure reduction of greater than or equal to 0.5 cm H2O using the P-Flex comfort mode

Completion date
01/10/2013

Eligibility

Key inclusion criteria
1. Male or Female, aged 21 years of age and above
2. Obstructive Sleep Apnoea with an Apnea Hypopnea Index (AHI) of greater than or equal to 30 confirmed by polysomnography
3. Epworth sleepiness scale (ESS) of greater than or equal to 11
4. Able to provide consent
5. Able to follow the instructions given by the investigator regarding using their APAP device and their participation in this study
6. Covered by National Health Insurance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Positive airway pressure (PAP) therapy is otherwise medically contraindicated: acute upper respiratory infection, encephalitis, sinusitis or middle ear infection or surgery of the upper airway, nose, sinus, or middle ear within the previous 90 days.
2. Untreated, non-OSA sleep disorders, including but not limited to; insomnia, Periodic Leg Movements (PLM) / Restless Legs Syndrome (RLS), Obesity Hypoventilation Syndrome (OHS), overlap syndrome and Central Sleep Apnoea (CSA) / Cheyne Stokes Respiration (CSR) associated with Heart Failure.
3. Treated Insomnia
4. Intake of central relevant drugs, sedatives, or other drugs which impair sleep
5. Previous exposure to positive airways pressure therapy
6. Acute dermatitis or other skin lesions or trauma interfering with the application of a mask
7. Unwilling to participate in the study
8. Participation in another clinical study in the past 4 weeks
9. Shift worker

Date of first enrolment
01/10/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
France

Study participating centre
IDRAL
59800 Lille
France
59800

Sponsor information

Organisation
Philips Home Healthcare Solutions (UK)

ROR

https://ror.org/04ktqp584

Funder(s)

Funder type
Industry

Funder Name
Philips Home Healthcare Solutions (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results	30/10/2015	21/01/2019	No	No