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Study of perception of a new generation of continuous positive airway pressure (CPAP) device, PR1-PFlex

Submission date
18/03/2013

Recruitment status
No longer recruiting

Registration date
04/04/2013

Overall study status
Completed

Last Edited
08/08/2013

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnea in its severe form is treated by Continuous Positive Airway Pressure (CPAP). CPAP delivers positive pressure in the upper airway of the patient through a nasal mask or nasal-oral mask and a circuit during sleep.
The benefits of CPAP treatment have been extensively researched. It has been established that the more a patient uses treatment during sleep the better the clinical benefit is. However, the number of patients not using the device properly or who stop using the device after one year is high. The major challenges of CPAP treatment are to reduce constraints surrounding the use of the device and to maximize the amount of time used during sleep.
The aim of the study is to assess the comfort and subjective satisfaction of patients using a CPAP new generation (PR1-PFlex) with advanced technology for comfort.

Who can participate?
Patients with Obstructive Sleep Apnoea Syndrome (OSAS) using an existing device.

What does the study involve?
The patients will undergo a medical examination. They will complete a series of questionnaires and data will be obtained from their current device. After seven days, they will be visited at home and the study device will be given to the patient and explained. After the study device has been used for about seven days the patient will be sent in the post some questionnaires to complete and a new data recording card. The patient will need to return the completed questionnaires and the data recording card from the study device to the investigator. Full instructions will be given to the patient.

What are the possible benefits and risks of participating?
The PR1-Pflex device has a current CE mark, is available for sale in Europe and will be used within the scope of its intended use in this study. The benefit to patients with OSAS is to use a more comfortable CPAP device which should significantly reduce the pressure level without impacting the effectiveness of treatment. Apart from known minor risks relating to CPAP, there are no additional risks or benefits.

Where is the study run from?
Centre du Sommeil
Département inter-hospitalier de Physiologie Explorations Fonctionnelles
Bichat Louis Mourier
Hôpital Bichat Claude Bernard
46 Rue Henri Huchard
75018 Paris, FRANCE

Hôpital Béclère
Service dExplorations Fonctionnelles Multidisciplinaires
157 rue de la Porte de Trivaux
92141 Clamart, FRANCE

Hôpital Ambroise Paré
Service de Physiologie/Explorations Fonctionnelles
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92104 Boulogne-Billancourt, FRANCE

Hôpital La Pitié Salpétrière
Laboratoire du Sommeil/pavillon Marguerite Bottard
47-83 Bd de l'Hôpital
75651 Paris Cédex 13, FRANCE

Hôpital Tenon
Service Explorations Fonctionnelles Multidisciplinaires
4 rue de la Chine
75020 Paris, FRANCE

Centre Hospitalier de Gonesse
Centre des E.F.N
25 rue Bernard Février
95500 Gonesse, FRANCE

Centre Hospitalier de Compiègne
Service de Pneumologie et Unité des pathologies du sommeil
8 Avenue Henri Adnot, ZAC de Mercières 3
60200 Compiègne, FRANCE

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Cabinet de Pneumologie
17 rue Rivière
33000 Bordeaux, FRANCE

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21 rue Estagnas
64204 Biarritz, FRANCE

Nouvelle Clinique de L'Union
Boulevard de Ratalens

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31240 L'Union, FRANCE

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332 avenue Frédéric Mistral
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Centre Hospitalier Nord de Marseille
Service de Pneumologie
Chemin des Bourrely
13915 Marseille, FRANCE

Centre Hospitalier Privé de Saint Brieuc
Polyclinique du Littoral
58 rue La Fayette
22000 Saint Brieuc, FRANCE

When is the study starting and how long is it expected to run?
It is anticipated that recruitment will start in May 2013. 110 participants will be enrolled for 5 months.

Who is funding the study?
Philips Home Healthcare Solutions (France).

Who is the main contact?
Ms Linda Makhlouf
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EAME12PhysioFlex02, 2012-A00978-35

Study information

Scientific Title
Prospective multicenter study of a new generation CPAP device, PR1-PFLEX in patients with Obstructive Sleep Apnea Syndrome.

Study objectives
The PR1-PFlex CPAP device will be perceived by patients as at least equivalent in terms of size, noise, ease of use, quality of sleep and overall satisfaction when compared to their existing device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for the Protection of Persons Ile de France VIII (Comité de Protection des Personnes Ile de France VIII), 05/11/2012, Ref: CPP: 12 09 84

Study design
Prospective multicenter study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions

Patients treated for OSA with a CPAP for which a change machine should be considered will be recruited during their annual follow-up visit.
During the inclusion visit are collected:
- The first questionnaire (called "Questionnaire de satisfaction PRE-TEST"), to assess patient satisfaction with respect to the device with which he was treated so far, is filled at the inclusion visit.
- The Epworth Sleepiness Scale.
- The Sleep Quality questionnaire (Saint Mary'Hospital Questionnaire) to assess subjective sleep quality patient.
- The compliance (data in hours/night and number of days/week), recorded by the machine on SD card and obtained by the embedded software of PPC and the P90.
The CPAP device is changed to the PR1-P Flex, which will be used for at least 7 days.
At the end of this period are collected (completed by the patient at home and sent to the investigator by mail):
- The second questionnaire (called "Questionnaire de satisfaction POST-TEST") to reassess the patient's satisfaction with respect to his former unit, evaluate the satisfaction of the PR1-P Flex, and assess his preference between the two devices
- The Epworth Sleepiness Scale
- The questionnaire to reassess subjective sleep quality patient, Saint Mary's Hospital Questionnaire
- The compliance data (in h/night and number of days/week), recorded by the machine on SD card and obtained by the embedded software of PPC and the P90.
The patient may keep the device PR1 P-Flex if desired, or return to the previous device.
The CRF will be completed by the physician investigator after each patient contact. It is from these data that will be calculated by statistical analysis of the test results.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The primary endpoint of this study is based on patient satisfaction. This satisfaction assessment will be by means of two satisfaction questionnaires (before and after use of the device Questionnaire (Questionnaire PRE-TEST and Questionnaire POST-TEST).

Secondary outcome measures
The secondary endpoints of the study are:
1. Assessing sleepiness (Epworth scale) and sleep quality (Saint Mary's Hospital Questionnaire)
2. Evaluate the data recorded by the device, such as:
2.1. Compliance and % sleep time
2.2. The residual AHI
2.3. The P90 represents the effective pressure required to remove obstructive events during at least 90% of the night.

Overall study start date
02/05/2013

Completion date

30/09/2013

Eligibility

Key inclusion criteria
1. Male or female, aged 18 years of age
2. Documented Obstructive Sleep Apnea Syndrome
3. Using CPAP with an auto-PAP mode at least 3 hours per night (data from the device)
4. CPAP should be replaced routinely by the home care provider or physicians decision
5. Able to provide consent
6. Able to follow the instructions given by the investigator
7. Covered by National Health Insurance

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110 patients

Key exclusion criteria
1. 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 and any non-indications usual and described in the manual
2. Untreated non-OSA sleep disorders
3. Intake of central relevant drugs, sedatives, or other drugs which impair sleep.
4. Acute dermatitis or other skin lesions or trauma interfering with the application of a mask
5. Unwilling to participate in the study
6. Participation in another clinical study in the past 4 weeks

Date of first enrolment
02/05/2013

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
France

Study participating centre
Centre du Sommeil
Paris
France
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Sponsor information

Organisation
Philips Home Healthcare Solutions (France)

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Sponsor type
Industry

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ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Philips Home Healthcare Solutions (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