

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

|                                        |                                                      |                                                                                                              |
|----------------------------------------|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>18/03/2013   | <b>Recruitment status</b><br>No longer recruiting    | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>04/04/2013 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>08/08/2013       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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 Bécclère

Service d'Explorations Fonctionnelles Multidisciplinaires

157 rue de la Porte de Trivaux

92141 Clamart, FRANCE

Hôpital Ambroise Paré

Service de Physiologie/Explorations Fonctionnelles

9 avenue Charles de Gaulle

92104 Boulogne-Billancourt, FRANCE

Hôpital La Pitié Salpêtrière

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

Polyclinique Saint Laurent

2 ter rue du Saint Laurent

35706 Rennes, FRANCE

Cabinet de Pneumologie

17 rue Rivière

33000 Bordeaux, FRANCE

Polyclinique Aguilera

21 rue Estagnas

64204 Biarritz, FRANCE

Nouvelle Clinique de L'Union

Boulevard de Ratalens

BP 24336 SAINT-JEAN  
31240 L'Union, FRANCE

Polyclinique des Fleurs  
332 avenue Frédéric Mistral  
83190 Ollioules, FRANCE

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 Makhoulf  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**

## 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

### Primary study design

Observational

### Study design

Prospective multicenter study

### Study type(s)

Treatment

### 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(s)**

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).

## **Key secondary outcome(s)**

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.

## **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

## **Healthy volunteers allowed**

No

## **Age group**

**Adult**

**Lower age limit**

18 Years

**Sex**

All

**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

75018

## **Sponsor information**

**Organisation**

Philips Home Healthcare Solutions (France)

**ROR**

<https://ror.org/05jz46060>

# **Funder(s)**

**Funder type**

Industry

**Funder Name**

Philips Home Healthcare Solutions (France)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration