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Pressure reduction during exhalation in sleep apnoea patients treated by continuous positive airway pressure (CPAP)

Submission date
15/09/2008

Recruitment status
No longer recruiting

Registration date
09/10/2008

Overall study status
Completed

Last Edited
30/12/2020

Condition category
Nervous System Diseases

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

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
EAMECFLEX2005

Study information

Scientific Title
Pressure reduction during exhalation in sleep apnoea patients treated by continuous positive airway pressure (CPAP)

Acronym
C-Flex Web

Study objectives
This French, multicentre, randomised controlled trial tested the hypothesis that pressure reduction during exhalation (C-Flex™) would improve continuous positive airway pressure (CPAP) compliance, comfort and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grenoble Ethics Committee granted approval on the 11th May 2005.

Study design
Randomised, single blind, controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Experimental: C-Flex™
Control: CPAP

The initial intervention will last for three months, after which patients on CPAP will be moved to C-Flex™ for a further 3 months. Those on C-Flex™ during the first 3 months will remain on C-Flex™ for the second 3 months. Total duration will therefore be six months for all patients.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Compliance, measured at baseline and after 3 and 6 months. Compliance was monitored by the machine and reported via a Smartcard and reader using the Encore pro system.

Secondary outcome measures
1. Daytime sleepiness, assessed using the Epworth Sleepiness Scale
2. Quality of life, assessed using a generic questionnaire (36-item short form health survey [SF-36]) and a questionnaire specific to obstructive sleep apnoea syndrome (Grenoble Sleep Apnoea Quality of Life [GrenobleSAQOL])

Measured at baseline and after 3 and 6 months.

Overall study start date
15/06/2005

Completion date
30/11/2006

Eligibility

Key inclusion criteria
1. Newly diagnosed sleep apnoea patients
2. Over 18 years of age, either sex
3. Referred for CPAP treatment by their consulting physician

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
218

Key exclusion criteria
1. Pregnant
2. Medically unstable
3. Predominantly central sleep apnoea

Date of first enrolment
15/06/2005

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
France

Study participating centre
20, rue Jacques Daguerre
Paris
France
92565

Sponsor information

Organisation
Respironics International, Inc. (France)

Sponsor details
20, rue Jacques Daguerre
Rueil Malmaison
Paris
France
92565

Sponsor type
Industry

Website
http://www.respironics.com/

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International, Inc. (France)

Funder Name
French Committee of Respiratory Diseases (Comité National contre les Maladies Respiratoires CNMR]) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009	30/12/2020	Yes	No