

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	☐ Prospectively registered
Registration date 09/10/2008	Overall study status Completed	☐ Protocol
Last Edited 30/12/2020	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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.

Primary study design

Interventional

Study design

Randomised, single blind, controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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