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Variable-pressure versus fixed-pressure continuous positive airway pressure (CPAP) treatment for patients with obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

Submission date
28/04/2009

Registration date
11/05/2009

Last Edited
24/02/2010

Recruitment status
No longer recruiting

Overall study status
Completed

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
2005/R/SL/01

Study information

Scientific Title
Randomised controlled trial of variable-pressure versus fixed-pressure continuous positive airway pressure (CPAP) treatment for patients with obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

Study objectives
Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) is a common illness affecting approx 4% of middle-aged men and 2% of middle aged women, who most frequently complain of symptoms of snoring and breathing pauses during sleep and daytime sleepiness. OSAHS is caused by relaxation of the upper airway during sleep, predisposing the airway to narrowing and eventual collapse. The restoration of airway patency is achieved by short arousals from sleep to allow breathing before sleep ensues again. The treatment of choice for OSAHS is continuous positive airway pressure (CPAP), which is a mechanical treatment involving the patient wearing a nasal mask during sleep, through which is blown a gentle airstream that splints the upper airway open, preventing collapse, breathing pauses, sleep disruption and dips in oxygenation.

This randomised controlled cross-over trial will seek to determine whether OSAHS patients on variable-pressure CPAP (AutoSet Spirit™) for six weeks have better outcomes over fixed-pressure CPAP for:
1. Patients' treatment preference
2. Patient-orientated function on treatment (objective and subjective sleepiness, quality of life, vigilance, side-effects, symptoms)
3. Clinician-orientated treatment success (CPAP use, CPAP pressure, residual Apnoea-Hypopnea Index [AHI], mask leak)
4. Direct economic costs (staff and patient time, equipment costs)
5. Indirect economic benefits (health utility/quality-adjusted life years [QALYs])

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian NHS Board, Lothian Local Research Ethics Committee 04, approved on 17 February 2005 (ref: 04/S1104/41)

Study design
Randomised double-blind (patients and researchers) cross-over single-centre trial

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

Interventions
This is a randomised double-blind cross-over trial with 6 weeks of fixed-pressure continuous positive airways pressure (CPAP) and 6 weeks of variable-pressure CPAP. The first two weeks of each treatment was taken as a wash-out period.

Eligible patients will be identified during the Dept of Sleep Medicine's weekly clinical review of cases, where full casenotes and investigations are available to ascertain inclusion and exclusion criteria. Consecutive eligible patients will be approached with information on the study and asked to consent to participation. Excluded or declining patients in the series will have reasons for these recorded for later post-hoc comparison with the recruited patient group.

Consenting patients will receive CPAP education and mask-fitting as per our usual practice and automated CPAP titration using Spirit units, to determine therapeutic pressure for fixed-pressure CPAP (95th centile of pressure profile, unless adjusted by clinical staff for technical reasons). Patients will be asked to complete Epworth and SF-36® Health Survey just before titration, as a contemporaneous measure of pre-treatment status. After titration study, all patients will be issued with a Spirit unit set in the appropriate treatment mode (fixed- or variable-pressure CPAP) for home use over the first 6 week treatment limb.

At the end of each 6 week treatment limb, patients are asked to attend with their Spirit CPAP units for a 3 hour session of testing, including breaks, and collecting the following measurements:
1. Objective sleepiness: Two 40-min Oxford Sleep Resistance (OSLER) tests (sleep resistance task)
2. Subjective sleepiness Epworth sleepiness scale
3. Vigilance Physiological vigilance test (PVT)
4. Symptom ratings Nocturnal and daytime symptoms
5. Health-related quality of life SF-36® Health Survey
6. CPAP side effects Edinburgh side-effects checklist
7. CPAP use and efficacy of Spirit CPAP units' memory (final 4 weeks):
7.1. CPAP use
7.2. CPAP pressure
7.3. Mask leak
7.4. Residual AHI on CPAP
8. At the last session patients will also be asked to rate treatment preference: variable-pressure or fixed-pressure CPAP

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Patient preference, recorded once at trial end and assessed using a chi-square test.

Secondary outcome measures
1. Patient-orientated effectiveness of treatment (sleepiness, symptoms, side-effects)
2. Physiologically-orientated effectiveness of CPAP (AHI, CPAP pressure, CPAP use)

Overall study start date
14/03/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Both males and females, between 18 and 70 years of age
2. CPAP naïve patients
3. Epworth Sleepiness Scale (ESS) >10 OR history of troublesome sleepiness when driving
4. AHI >15 on polysomnography or AHI/respiratory disturbance index (RDI) >25 on limited sleep study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Severe neurological deficit sufficient to compromise CPAP usability or understanding
2. Significant co-morbidity (severe or unstable respiratory, neurological, metabolic or cardiac disease)
3. Co-existing sleep disorder such as narcolepsy, periodic limb movement syndrome
4. Contra-indications to CPAP use including recent pneumothorax

Date of first enrolment
14/03/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Respiratory Medicine
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
Lothian NHS Board (UK)

Sponsor details
Lothian Local Research Committee 04
Deaconess House
148 Pleasance
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EH8 9RS

Sponsor type
Hospital/treatment centre

Website
http://www.nhslothian.scot.nhs.uk/aboutus/ourorganisation/nhsboard/lhb.asp

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Industry

Funder Name

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	01/02/2010		Yes	No