ISRCTN39453867 https://doi.org/10.1186/ISRCTN39453867

Comparison of adherence of different nasal masks in Obstructive Sleep Apnea patients treated by CPAP therapy

Submission date 17/04/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/04/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/04/2015	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnoea (OSA) is a very common condition characterised by repetitive episodes of complete or partial upper airway obstruction during sleep. Continuous positive airway pressure therapy (CPAP) is the best available treatment for OSA: it helps people breathe more easily during sleep by delivering a constant level of pressure. However CPAP is not always well tolerated and 8–15% of patients stop treatment after one night. The mask is an essential element of CPAP and mask discomfort is often the reason for stopping CPAP. Also, the choice of initial mask is critical to avoid repeated interface changes that impact on patient motivation and increase costs. There have been few studies on the influence of the choice of mask on CPAP. The aim of this study is to compare different nasal masks in patients with OSA treated by CPAP.

Who can participate?
Newly-diagnosed sleepy OSA patients.

What does the study involve?
Participants are allocated to one of two groups:
Group 1 (MFX group) receives CPAP (AutoSet, ResMed) via ResMed Mirage FX® nasal mask.
Group 2 (Control group) receives CPAP (AutoSet, ResMed) via Fisher & Paykel Zest® or HC407®; or Philips Respironics EasyLife® nasal mask.

What are the possible benefits and risks of participating?
Possible benefits are better mask comfort and CPAP therapy adherence. No additional risk.

Where is the study run from?
4 centres in France

When is the study starting and how long is it expected to run for?
March 2011 to December 2013

Who is funding the study?
ResMed (France)

Who is the main contact?
Dr Laurent Morin

Contact information

Type(s)
Scientific

Contact name
Dr Laurent Morin

Contact details
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69791

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Impact of different nasal masks on CPAP therapy for obstructive sleep apnea: a randomized comparative trial

Study objectives
Patient interface is important for the success of continuous positive airway pressure (CPAP) but few trials have examined the influence of mask choice on CPAP. This study compared the impact of different nasal masks on CPAP in patients with newly-diagnosed obstructive sleep apnea (OSA) who were randomized to receive CPAP via different first-line nasal masks.

Ethics approval required
Old ethics approval format

Ethics approval(s)

French Ethicd Committee (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé n: 11.414) and authorization of the French Data Processing Commission (Commission Nationale de L'Informatique et des Libertés n: 911341), 11 /07/2011, ref number 11.414

Study design
Muticentre randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

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
Newly-diagnosed obstructive sleep apnea (OSA) patients treated by CPAP

Interventions
2 parallel arms randomized with a ratio 2:3
Group 1: ResMed Mirage FX nasal mask
Group 2: Fisher & Paykel Zest® or HC407®; or Philips Respironics EasyLife®
Patients treated with CPAP ResMed S9 AutoSet

Intervention Type
Device

Primary outcome measure
Mask acceptability, defined as continued use of the nasal mask assigned at randomization, at 3-month follow-up

Secondary outcome measures
1. CPAP compliance at 3-month follow up measured automatically by the device
2. Home Care Provider interventions measured by number and duration of phone calls and home visits
3. Causes of both mask and CPAP failure

Overall study start date
15/03/2011

Completion date

30/12/2013

Eligibility

Key inclusion criteria
1. Newly-diagnosed Obstructive Sleep Apnoea / Hypopnoea Syndrome (OSAHS) patients
2. Daytime sleepiness and ≥3 of listed symptoms (snoring, morning headaches, reduced alertness, libido disorders, hypertension or nocturia) associated with an apnea-hypopnea index (AHI) of >30/h or 5-30/h with ≥10 respiratory event-related arousals with an increase in respiratory effort documented by polysomnography (PSG),
3. Central apnea index of ≤20%,
4. Absence of nocturnal mouth leaks detected during CPAP treatment initiation,
5. No known allergy to silicone,
6. Fitted with an automatic positive airway pressure (APAP) device (S9 AutoSet; ResMed)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Sample size: 228 patients (4 centers)

Key exclusion criteria
1. Refusal or unable to participate
2. First-line nasal mask other than those being assessed
3. Patient previously treated with CPAP/APAP or noninvasive positive pressure ventilation
4. Has undergone Ear, nose and throat (ENT) surgery within the previous 6 weeks
5. Significant epistaxis in the previous 6 months,
6. Patient participating in another clinical trial

Date of first enrolment
01/01/2012

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
France

Study participating centre

Univ'Air Medical
St Germain-en-Laye
France
78100

Study participating centre
Assistance Médicale Spécialisée (AMS)
Pau
France
64000

Study participating centre
Santeol
Strasbourg
France
67000

Study participating centre
MBAR Marc Baucher Assistance Respiratoire
Ballan-Miré
France
37510

Sponsor information

Organisation
ResMed

Sponsor details
Part Technologique de Lyon
292 Avenue Jacques Monod
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
ResMed

Results and Publications

Publication and dissemination plan
Publication of main results planned mid-2015 in peer-reviewed journal.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available