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A comparative study of humidification and a nasal spray for the treatment of nasal symptoms experienced by patients using continuous positive airway pressure (CPAP) via a mask

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/09/2014	Nervous System Diseases	[ ] Record updated in last year

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
N0542102350

Study information

Scientific Title

Study objectives
The research will compare outcomes for patients treated with syntaris nasal spray and heated humidification with regard to:
1. Incidence and severity of self-assessed nasal dryness, runny nose, blocked nose
2. Compliance with CPAP therapy
3. Annualised cost of treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised 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
Nervous System Diseases: obstructive sleep apnoea (OSA)

Interventions
32 patients will be recruited from new patients presenting with OSA who are to be treated with CPAP.

The study arms are:
1. Nasal spray
2. Headed humidification

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Patients' nasal symptoms will be assessed using a self-scored scale. This will determine baseline symptoms, the effects of CPAP and of nasal sprays/humidification

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2002

Completion date
31/08/2003

Eligibility

Key inclusion criteria
32 patients will be recruited from new patients presenting with OSA who are to be treated with CPAP

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
32

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/2002

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
RSSC
Cambridge
United Kingdom
CB3 8RE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Papworth Hospital NHS Trust (UK)

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