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

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Nervous System Diseases	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 summaryNot provided at time of registration