

Randomised controlled trial (RCT) of continuous positive airways pressure therapy (CPAP) versus placebo in the treatment of sleep apnoea

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/01/2010	Condition category Respiratory	☐ 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

SPGS764

Study information

Scientific Title

Study objectives

Nasal continuous positive airway pressure (NCPAP) is widely used as a treatment for obstructive sleep apnoea without previous good evidence from a randomised controlled trial of the therapy against a well matched placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory tract diseases: Other respiratory tract disease

Interventions

Therapeutic NCPAP or sub-therapeutic NCPAP for 1 month

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Improvements in excessive daytime sleepiness and self-reported health status

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/07/2000

Eligibility

Key inclusion criteria

1. 101 men attending Osler Chest Unit, Churchill Hospital Epworth
2. Sleepiness score of >10 and 10hr of >4% SaO2 dips on overnight sleep study
3. Aged between 30-65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/03/1997

Date of final enrolment

01/07/2000

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Health Services Research Unit

Oxford

United Kingdom

OX3 7LF

Sponsor information**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

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	01/03/2000		Yes	No
Results article	results	01/11/2003		Yes	No