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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 [X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Improvements in excessive daytime sleepiness and self-reported health status

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/1997

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% Sa02 dips on overnight sleep study
3. Aged between 30-65 years

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
101

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (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

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