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

| Submission date               | Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------------------|---|--|--|--|
| 23/01/2004                    |   | ☐ Protocol                                 |  |  |
| Registration date             | Overall study status                    | Statistical analysis plan                  |  |  |
| 23/01/2004                    | Completed                               | [X] Results                                |  |  |
| <b>Last Edited</b> 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

### Contact name

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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              |