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Napping behaviour in sleep apnoea: a transcultural study in older people

Submission date
12/01/2012

Recruitment status
No longer recruiting

Registration date
28/02/2012

Overall study status
Completed

Last Edited
07/04/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea syndrome (OSAS) is a condition where the walls of the throat relax and narrow during sleep, interrupting normal breathing. These repeated sleep interruptions can make patients with OSAS feel very tired during the day, causing them to take frequent naps. OSAS can be treated with continuous positive airway pressure (CPAP). This involves wearing a mask that delivers a continuous supply of compressed air that prevents the throat from closing. The aim of this study is to examine the effect of CPAP on napping behaviour in OSAS patients in two different ethnic populations.

Who can participate?
Scottish and Taiwanese patients with OSAS, aged 60 and over, who nap at least 3 times per week with average nap duration of at least 30 minutes.

What does the study involve?
Patients are randomly allocated to one of two groups. One group is treated with CPAP and best supportive care for 12 weeks. The other group is treated with best supportive care for 6 weeks, then CPAP and best supportive care for another 6 weeks. Best supportive care includes normal medical treatment and information about weight loss, stopping smoking, drinking less alcohol, changing sleeping posture and sleep hygiene. Both groups undergo tests at the start of the study and at follow-up. The tests evaluate sleep behaviour, mood and anxiety, and quality of life. All participants undergo 2 weeks of actigraphy (sleep monitoring) before hospital visits. Sleep diaries are recorded over the study period.

What are the possible benefits and risks of participating?
All participants receive detailed advice on managing their OSAS with improved diet, exercise and regular sleep patterns. We may find during the tests that something needs further investigation or treatment that would not have otherwise been found. CPAP is generally very well tolerated. Sometimes it can cause nasal dryness/discomfort, nasal discharge, a dry mouth (and dribbling), facial discomfort and, rarely, ulceration due to poor mask fitting. These effects can be minimised by the use of humidification and careful mask fitting.

Where is the study run from?
1. Royal Infirmary of Edinburgh (UK)
2. Kaohsiung Medical University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
February 2012 and October 2012

Who is funding the study?
National Science Council (Taiwan)

Who is the main contact?
Dr Chung-Yao Hsu

Contact information

Type(s)
Scientific

Contact name
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Scientific

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United Kingdom
EH16 4SA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Napping Behaviour in Sleep Apnoea (NBSA): a randomised transcultural study in older people

Acronym
NBSA

Study objectives
Napping behaviour in obstructive sleep apnoea (OSAS) patients may reflect a compensatory reaction to sleep deprivation or sleep interruption. If sleep deprivation or sleep interruption due to disturbed breathing improve after continuous positive airway pressure (CPAP) treatment, napping behaviour may decrease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 01, 21/02/2012, ref: 12/SS/0017

Study design
Randomised single-blind parallel study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnoea syndrome (OSAS)

Interventions
1. An early CPAP group: CPAP + best supportive care (BSC) for 12 weeks
2. A delayed CPAP group: BSC for 6 weeks initially then CPAP + BSC will be combined for another 6 weeks.

BSC includes normal medical treatment and information about weight reduction, smoking cessation, reducing alcohol consumption, change in sleeping posture and sleep hygiene.

Intervention Type
Device

Primary outcome measure
Change in weekly nap frequency and duration every 6 weeks in both groups

Secondary outcome measures
1. CPAP compliance during CPAP intervention in both groups
2. Change in Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) scores
3. Change in RAND-36 scores
4. Change in Hospital Anxiety and Depression Scale (HADS) scores
Measured every 6 weeks in both groups
5. Change in reaction time of Psychomotor Vigilance Task (PVT) assessed post intervention

Overall study start date
15/02/2012

Completion date
31/10/2012

Eligibility

Key inclusion criteria
1. Aged 60 years and over
2. Have apnoea-hypopnoea index (AHI) ≥ 15
3. Nap at least 3 times per week with average nap duration of at least 30 minutes

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
30 in United Kingdom, 30 in Taiwan

Key exclusion criteria
1. Have previous exposure to continuous positive airway pressure (CPAP) therapy
2. Are unable to give written informed consent or comply with the protocol
3. Are on central nervous system (CNS)-active drug treatment (e.g., hypnotic and antiepileptic drugs) that causes significant daytime sleepiness or cognitive impairment
4. Have an unstable medical or psychiatric illness
5. Have moderate to severe respiratory disease that affects activities of daily living or awake SpO2 less than 92%

Date of first enrolment
15/02/2012

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
Taiwan

United Kingdom

Study participating centre
No.100, Tzyou 1st Road
Kaohsiung
Taiwan
80754

Sponsor information

Organisation
Kaohsiung Medical University Hospital (Taiwan)

Sponsor details
100, Shih-Chuan 1st Road
Kaohsiung
Taiwan
80708

Sponsor type
Hospital/treatment centre

Website
http://www.kmuh.org.tw

Organisation
Department of International Cooperation (Taiwan)

Sponsor details
National Science Council
Rm2205 106 Ho-Ping E. Rd. Sec. 2
Taipei
Taiwan
10622

Sponsor type
Government

Organisation
Kaohsiung Medical University Chung-Ho Memorial Hospital

Sponsor details

Sponsor type
Not defined

Website
http://www.kmuh.org.tw/

ROR
https://ror.org/02xmkec90

Funder(s)

Funder type
Government

Funder Name
National Science Council (NSC 99-2911-I-037-004)

Alternative Name(s)
National Science Council, Taiwan, National Science Council of Taiwan, NSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

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