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Neurocognitive and health-related quality of life outcomes of nocturnal oxygen supply in chronic obstructive pulmonary disease patients with sleep-related oxygen desaturation

Submission date
07/03/2006

Recruitment status
No longer recruiting

Registration date
11/04/2006

Overall study status
Completed

Last Edited
11/04/2006

Condition category
Respiratory

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

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
IAS-PnN1-2006

Study information

Scientific Title

Acronym
GIRON

Study objectives
Nocturnal oxygen supply will prevent the consequences of sleep-related hypoxemia (i.e. neurocognitive and health-related quality of life decline) in severe to very severe chronic obstructive pulmonary disease (COPD) patients presenting sleep-related oxygen desaturation. This decline will become similar to that seen in those severe to very severe COPD patients without nocturnal desaturation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Institute of Health Assistance (Institut d'Assistència Sanitària) (IAS), Institutional Review Board (IRB) reviewed the protocol and reported its approval on 27/04/2004, reference number: CEIC-IAS 06/2004

Study design
Prospective, randomised clinical trial and prospective case-control study

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
COPD with and without nocturnal desaturation

Interventions
All patients will receive standard care, but nocturnal desaturators will be randomized to receive oxygen during sleep or standard care only. Neurocognitive function, blood/urine analysis and electrocardiogram will be assessed at baseline and at 18 months. Health-related quality of life,

lung function, six-minute walking test, nocturnal oxymetry and respiratory and sleep-related symptoms will be assessed at baseline and at six-month intervals.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Neurocognitive function by means of a battery of tests:
1. Trail making test
2. Wechsler adult intelligence scale (WAIS)
3. Wechsler memory scale-revised (WMSR) test
4. Verbal fluency test
5. Rey complex figure test (RCFT)
6. Rey auditory verbal learning test (RAVLT)
7. National adult reading test (NART)
8. Repeatable battery for the assessment of neuropsychological status (RBANS)
9. Luria's premotor test performance

Secondary outcome measures
1. Health-related quality of life (St. George’s respiratory questionnaire)
2. Anxiety (state-trait anxiety inventory [STAI])
3. Depression (Beck depression inventory [BDI])
4. Exercise capacity (walking test)
5. Sleepiness (Epworth scale)
6. Dyspnea (Medical Research Council [MRC] scale)
7. Diurnal oxygen and carbonic anhydride blood pressures
8. Nocturnal urinary norepinephrine
9. Exacerbation rate
10. Hospitalization days
11. Mortality

Overall study start date
08/03/2006

Completion date
07/03/2009

Eligibility

Key inclusion criteria
1. Severe to very severe stable COPD
2. Age 60 to 80 years
3. With a resting awake pO2 between 60 and 80 mmHg, with (cases) or without (controls) sleep-related oxygen desaturation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
216 (144 nocturnal desaturators)

Key exclusion criteria
1. Clinically significant obstructive sleep apnea-hypopnea syndrome
2. Alcoholism
3. Anemia
4. Dementia
5. Cirrhosis
6. Obesity
7. Active psychiatric disease
8. Abnormal thyroid function
9. Stroke
10. Chronic systemic steroid therapy
11. Malignancy

Date of first enrolment
08/03/2006

Date of final enrolment
07/03/2009

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Santa Caterina
Salt
Spain
17019

Sponsor information

Organisation
Institute of Health Assistance (Institut d'Assistència Sanitària [IAS]) (Spain)

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Sponsor type
Industry

Website
http://www.ias.scs.es

ROR
https://ror.org/058css875

Funder(s)

Funder type
Industry

Funder Name
IAS

Funder Name
Grants from:

Funder Name
Catalan Society of Pneumology 2005 (Societat Catalana de Pneumologia [SOCAP] 2005)

Funder Name
Spanish Society of the Pathology of the Respiratory System 2005 (Sociedad Española de Patología del Aparato Respiratorio [SEPAR] 2005)

Funder Name
Spanish Company of Air Products and Chemicals Inc. (Sociedad Española de Carburos Metálicos S. A.)

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