

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/04/2006	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration