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Association between cardiovascular risk and moderate-severe obstructive sleep apnea in Chile

Submission date
12/07/2019

Recruitment status
Recruiting

Registration date
24/07/2019

Overall study status
Ongoing

Last Edited
04/09/2023

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 apnea (OSA) is a breathing condition with an increased cardiovascular (heart disease) risk. especially those with moderate-severe OSA. Recent publications describe different subtypes of patients at the same OSA severity. In this setting, the presence of OSA and cardiovascular disease could define a potentially different phenotype with an increased risk of cardiovascular mortality. Other phenotypes are related to a different profile of patients according to a symptom-based approach, these patients report excessive sleepiness, snoring and high Epworth sleepiness scale. This subtype was independently associated with increased mortality risk. However, the prevalence of cardiovascular comorbidities and OSA subtypes in the Latino/Hispanic population is unclear. The aim of this study is to describe different subtypes of moderate-severe OSA in Chilean patients and to explore the association between these subtypes and cardiovascular comorbidities.

Who can participate?
Patients over the age of 18 referred for the sleep study because of the clinical suspicion of OSA (snoring symptoms, apneas observed by bed partner or excessive daytime sleepiness or major cardiovascular comorbidities)

What does the study involve?
The study includes participants with a recent diagnosis of moderate-severe OSA after a home sleep apnea test. Patients with mild and no OSA are defined as the control group. The aim is to define potential subtypes of patients using symptoms-based, oximetric-based and clinical-based approaches. The researchers also plan to describe different profiles of patients with moderate-severe OSA in Chile such as the elderly population, the female population, among others. Finally, the study explores the association between different oximeter measures reported in HSAT and cardiovascular outcomes, including mortality.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. Participants will receive the usual care.

Where is the study run from?
Clínica Las Condes, Santiago (Chile)

When is the study starting and how long is it expected to run for?
June 2009 to June 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E012018

Study information

Scientific Title
Prevalence of cardiovascular comorbidities and association with different subtypes of Chilean patients with moderate-severe Obstructive Sleep Apnea in Santiago (SantOSA)

Acronym
SantOSA

Study objectives
The researchers hypothesise that in Chilean patients with moderate-severe OSA, patients report different subtypes (phenotypes) according to clinical manifestations commonly found at sleep clinics and this association may be linked to an increased cardiovascular risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved January 2018, Ethics Committee of the Institution the Institution Review Board (Clinica Las Condes, Estoril 450, Las Condes, Santiago, Chile, ZIP: 7591047; Tel: +56 (0) 226103279; Email: cetica-secre@clinicalascondes.cl), IRB: 00008758

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Obstructive sleep apnea

Interventions
The researchers developed a prospective cohort study of participants aged >18 years since 2009 who were prospectively included to date in a single tertiary center. They will include all participants who were referred for the sleep study who performed an ambulatory home sleep apnea test (HSAT) because of the clinical suspicion of OSA (snoring symptoms, apneas observed by bed partner or excessive daytime sleepiness or major cardiovascular comorbidities).

Prior to the HSAT, a clinical examination and symptom standardized questionnaire was applied with the purpose of evaluating their sleep schedule, degree of daytime sleepiness, snoring, apnea observed by a bed partner, insomnia, episodes of nocturnal suffocation, and morning headache in addition to ESS. The study will include sociodemographic data, information about habits (tobacco and alcohol use), and anthropometric data (such as weight, height, body mass index (BMI) and neck circumference) were also recorded. The study also included the Flemons predictive model score (adjusted by neck circumference), nasal obstruction symptoms evaluation (NOSE), STOP-BANG and comorbidity characteristics at baseline (diagnosis of hypertension, T2DM, CHD, DLP, and stroke) and depression will be evaluated using the BECK questionnaire.

The researchers standardized the HSAT using an Embletta MPR equipment ([Embla Systems, USA) following the current recommendations and requirements of scientific societies for level III studies by American Society of Sleep Medicine (ASSM). OSA diagnosis requires an apnea-hypopnea index > 5 ev/hr, between 5-15 ev/hr is mild OSA and moderate-severe OSA requires an AHI > 15 ev/hr.

The plan is to categorize the data according to sleep apnea test results in two groups of analysis: the study group (moderate-severe OSA) and the control group (no OSA – mild OSA), for the control group, patients with other sleep apnea disorders after sleep study (including polysomnogram) study.

For a comprehensive analysis of different subtypes of patients, the researchers will explore different clinical subtypes through cluster analysis. For this purpose, they plan to develop a Latent class analysis, using a two-step auto-clustering process, and the number of clusters with the lowest Bayesian information will be selected as the number of clusters for further analysis. They plan to perform a sensitive analysis in order to define potentially subtype using: 1) a symptoms-based approach, 2) an oximetric-based approach and 3) a clinical-based approach.

The researchers also plan to perform a description of different profile of patients with moderate-severe OSA in Chile such as elderly population, female population, among others. Finally, they will explore the association between different oximeter measures reported in HSAT and cardiovascular outcomes, including mortality.

Intervention Type
Other

Primary outcome measure
1. All-cause mortality measured through a review of the national register database (https://www.registrocivil.cl) at 3, 5 and 10 years
2. Cardiovascular mortality measured through a review of the national register database (https://www.registrocivil.cl) at 3, 5 and 10 years

Secondary outcome measures
1. New onset of hypertension measured by either medical record or telephone consultation at 5 and 10 years
2. New onset of T2DM measured by either medical record or telephone consultation at 5 and 10 years
3. New onset of CHD measured by either medical record or telephone consultation at 5 and 10 years
4. New onset of atrial fibrillation measured by either medical record or telephone consultation at 5 and 10 years

Overall study start date
01/06/2009

Completion date
31/12/2035

Eligibility

Key inclusion criteria
1. Participants aged >18 years
2. Referred for the sleep study because of the clinical suspicion of OSA (snoring symptoms, apneas observed by bed partner or excessive daytime sleepiness or major cardiovascular comorbidities)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3000 participants

Key exclusion criteria
1. Participants with other sleep disorders such as periodic limb movements of sleep (PLMS), NREM and arousal, REM and hypoxia, arousal and poor sleep
2. Participants who refuse to sign the consent form

Date of first enrolment
01/08/2009

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Chile

Study participating centre
Clinica Las Condes
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/00j5bwe91

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The researchers plan to publish their results after a peer-review process. The results will provide information for future studies that clinicians could use to make patient-centred decisions and that healthcare managers, administrator and policymaker could use to guide allocation.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	oximetric parameter sub-analysis results	01/03/2021	03/04/2020	Yes	No
Interim results article		28/07/2023	04/09/2023	Yes	No
Interim results article		02/07/2021	04/09/2023	Yes	No
Interim results article		04/01/2021	04/09/2023	Yes	No
Interim results article		03/09/2020	04/09/2023	Yes	No
Interim results article		10/04/2020	04/09/2023	Yes	No