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Sleep apnea phenotypes among Latin American women

Submission date	Recruitment status	[X] Prospectively registered
01/09/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/09/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/09/2023	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Obstructive sleep apnea (OSA) occurs when the muscles that support the soft tissues in the throat, such as the tongue and soft palate, temporarily relax and cut off breathing during sleep. This study aims to understand the clinical phenotypes of the Hispanic/Latino community with OSA. In particular, the researchers are trying to identify what aspects of OSA adversely affect the cardiovascular system. In parallel, they will try to understand why recent studies in sleep apnea failed to show the effectiveness of CPAP, the gold standard treatment for OSA, in reducing the risk of major outcomes.

One reason that the impact of OSA on health outcomes remains disputed is that the golden standard metric, such as apnea-hypopnea index (AHI), used to quantify OSA severity, fails to capture the key aspects of OSA (frequent decreases of oxygen in the blood and arousals from sleep) that have negative effects on the cardiovascular system.

The aims of this study are to: 1) provide clinically and physiologically informed metrics to capture the OSA burden among Latin American women, 2) establish their generalizability in this minority group, and 3) supply clinicians with validated predictive models to assess OSA risk in Latin American women. This will enhance patient selection, involve this underrepresented group, and improve quality of life and health outcomes.

Who can participate?

Women over the age of 18 years with suspected OSA (snoring symptoms, apneas observed by bed partner or excessive daytime sleepiness or major cardiovascular illnesses)

What does the study involve?

The aim is to define potential subtypes of patients using symptoms-based, oximetric-based, and clinical-based approaches.

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?

Brigham and Women's Hospital (USA)

When is the study starting, and how long is it expected to run for?
September 2022 to October 2024

Who is funding the study?
1. The Chest Foundation (USA)
2. Universidad de Concepcion (Chile)

Who is the main contact?
Dr Gonzalo Labarca, glabarcat@gmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
128269

Study information

Scientific Title
Phenotyping Obstructive Sleep Apnea in Latin American women: The Latin American Sleep Network (LATAM Sleep Net)

Acronym
LATAM - OSA in women

Study objectives
The central hypothesis is that sleep apnea-specific hypoxic burden (SASHB) and delta heart rate (ΔHR) can identify an OSA phenotype among Latin American women with an increased risk of CPAP adherence in the short term and different burden of comorbidities. This hypothesis was formulated based on our preliminary solid data, including other communities and most males, in which SASHB was associated with worse health outcomes. In addition, ΔHR predicted increased cardiovascular outcomes and their combination provided more robust findings than the two measures in isolation. This project will examine how SASHB and ΔHR are distributed across women and modify CPAP adherence using prospective data from 16 Latin American sleep clinics.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/09/2022, Mass General Brigham IRB (399 Revolution Drive, Suite 710, Sommerville, 02145, United States of America; +1 (0)857 282 1900; IRB@partners.org), ref: 2022P002262

Study design
Multicenter prospective cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Prevention

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 will determine the following exposures from the raw signal:
1. Sleep Apnea-Specific Hypoxic Burden (SASHB): This metric encapsulates the frequency of upper airway obstructions during sleep (like the AHI) and the duration and depth of respiratory event-related oxygen desaturations. The SASHB is quantified by summing the area under the SpO curve associated with individual apneas and hypopneas. The total sum is then divided by the sleep duration, yielding units of minutes of % desaturation per hour of sleep (%·min/h).
2. OSA-Specific Heart Rate Response (ΔHR): The ΔHR is estimated using pulse signals derived from the photoplethysmography used in the pulse oximetry sensor. Consistent with previous studies, ΔHR is defined as the difference between a maximum heart rate during a subject-specific search window and an event-related minimum heart rate (the minimum heart rate during apneas/hypopneas). Finally, individual-level ΔHR is defined as the mean of all event-specific responses.

Intervention Type
Not Specified

Primary outcome measure
Sleep apnea-specific hypoxic burden (SASHB) and delta heart rate (ΔHR) measured using the raw data from the sleep test at baseline

Secondary outcome measures
CPAP compliance measured using CPAP device compliance report at 1 month after CPAP treatment

Overall study start date
01/09/2022

Completion date
01/10/2024

Eligibility

Key inclusion criteria
Women with suspected obstructive sleep apnea

Participant type(s)
Patient

Age group
Adult

Lower age limit

15 Years

Upper age limit
100 Years

Sex
Female

Target number of participants
500

Key exclusion criteria
1. Other sleep disorders such as periodic limb movement, narcolepsy, and parasomnias
2. Severe pulmonary disease

Date of first enrolment
01/09/2023

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
Argentina

Bolivia

Chile

Colombia

Costa Rica

Mexico

Peru

Uruguay

Study participating centre
Pontificia Universidad Catolica de Chile
Avda. Libertador Bernando O'Higgins 340
Santiago
Chile
8320000

Study participating centre
Hospital Clinico Dra. Eloisa Diaz
Avenida Froilán Roa N°6542, La Florida
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Universidad de Concepcion
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Hospital Faro del Mayab/Christus Muguerza
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Study participating centre
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Study participating centre
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Pellegrini, 28 de Julio &, Trelew
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Sponsor information

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Brigham and Women's Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.brighamandwomens.org/

ROR
https://ror.org/04b6nzv94

Funder(s)

Funder type
University/education

Funder Name
American College of Chest Physicians

Alternative Name(s)
CHEST, ACCP CHEST

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Funder Name
Universidad de Concepción

Alternative Name(s)
University of Concepcion, UdeC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Chile

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-centered decisions and that healthcare managers, administrators, and policymakers could use to guide allocation.

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study during this study will be available on request from Dr Gonzalo Labarca (glabarcat@gmail.com).
Type of data that will be shared: Raw signal, de-identified baseline information after signing a data user agreement (DUA).
Dates of availability: From December 2024
All data was de-identified.

IPD sharing plan summary
Available on request