

# Sleep apnea phenotypes among Latin American women

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/09/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/09/2023	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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, glabarc@gmail.com

## Contact information

### Type(s)

Principal investigator

### Contact name

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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 ( $\Delta$ HR) 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,  $\Delta$ HR predicted increased cardiovascular outcomes and their combination provided more robust findings than the two measures in isolation. This project will examine how SASHB and  $\Delta$ HR 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, Somerville, 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

**Study type(s)**

Prevention

**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 ( $\Delta$ HR): The  $\Delta$ HR is estimated using pulse signals derived from the photoplethysmography used in the pulse oximetry sensor. Consistent with previous studies,  $\Delta$ HR 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  $\Delta$ HR is defined as the mean of all event-specific responses.

### **Intervention Type**

Not Specified

### **Primary outcome(s)**

Sleep apnea-specific hypoxic burden (SASHB) and delta heart rate ( $\Delta$ HR) measured using the raw data from the sleep test at baseline

### **Key secondary outcome(s)**

CPAP compliance measured using CPAP device compliance report at 1 month after CPAP treatment

### **Completion date**

01/10/2024

## **Eligibility**

### **Key inclusion criteria**

Women with suspected obstructive sleep apnea

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

15 years

### **Upper age limit**

100 years

### **Sex**

Female

### **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

Santiago

Chile

8240000

**Study participating centre****Universidad de Concepcion**

Víctor Lamas 1290

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**Study participating centre**  
**Complejo Asistencial Dr. Victor Rios Ruiz**  
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4451055

**Study participating centre**  
**Clinica Davila**  
Av. Recoleta 464, Recoleta  
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**Study participating centre**  
**Clinica Las Condes**  
Estoril 450, Las Condes  
Santiago  
Chile  
7591047

**Study participating centre**  
**Fundación Neumológica Colombiana**  
Bogota  
Colombia  
13B 161 85

**Study participating centre**  
**Hospital Nacional Arzobispo Loayza**  
Av. Alfonso Ugarte 848  
Lima  
Peru  
15082

**Study participating centre**  
**Centro Privado de Medicina Respiratoria de Parana**  
Petrona Rosende 2394, E3100 Paraná, Entre Ríos  
Parana

Argentina  
E3100

**Study participating centre**

**Hospital Universitario Austral**

Av. Pres. Juan Domingo Peron 1500, Pilar Centro  
Buenos Aires  
Argentina  
B1629

**Study participating centre**

**Hospital Faro del Mayab/Christus Muguerza**

Calle 24 S/N, Temozon Norte, Santa Gertrudis Copo  
Merida  
Mexico  
97305

**Study participating centre**

**Hospital de Clínicas**

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Montevideo  
Uruguay  
11600

**Study participating centre**

**Hospital Mexico**

San José 267-1005  
San Jose  
Costa Rica  
10103

**Study participating centre**

**Instituto Neumologico del Oriente**

Cl. 53 #31-30, Sotomayor  
Bucaramanga  
Colombia  
52136

**Study participating centre**

**Clínica Anglo Americana**

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Lima

Peru

15073

**Study participating centre****Caja Nacional de Salud**

Av. Mariscal Santa Cruz Esq. Almirante Grau #123 La Paz

La Paz

Bolivia

4389464

**Study participating centre****Hospital Presidente Peron**

Anatole France 773, Sarandí

Buenos Aires

Argentina

B1872AWK

**Study participating centre****Hospital Zonal de Trelew**

Pellegrini, 28 de Julio &, Trelew

Chubut

Argentina

u9100auo

## Sponsor information

**Organisation**

Brigham and Women's Hospital

**ROR**

<https://ror.org/04b6nztv94>

## Funder(s)

**Funder type**

University/education

**Funder Name**

American College of Chest Physicians

**Alternative Name(s)**

CHEST, ACCP CHEST, ACCP

**Funding Body Type**

Government 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

**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 (glabarc@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