# Proximal Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea in the OSPREY Study: A Randomized Controlled Trial

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## Key Takeaway

**Proximal hypoglossal nerve stimulation (pHGNS) greatly reduced breathing interruptions and improved blood oxygen levels during sleep, and improved patient-reported daytime sleepiness symptoms in the only randomized double-blind clinical trial of adults with moderate-to-severe obstructive sleep apnea (OSA) to date**

LivaNova

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**Abbreviations:** AHI, Apnea-Hypopnea Index; BMI, body mass index; CCC, complete concentric collapse; CGI-I, Clinician Global Impression of Improvement; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; GLP-1, glucagon-like peptide-1; ODI, Oxygen Desaturation Index; OSA, obstructive sleep apnea; pHGNS, proximal hypoglossal nerve stimulation; PROMIS-SDI, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Index; PROMIS-SRI, Patient-Reported Outcomes Measurement Information System Sleep-Related Impairment.

## Why Was This Study Conducted?

**People with OSA globally:** 1 billion

**Major long-term potential health consequences:** cardiovascular events, stroke, metabolic syndrome, cognitive impairment and dementia, injury from accidents due to sleepiness

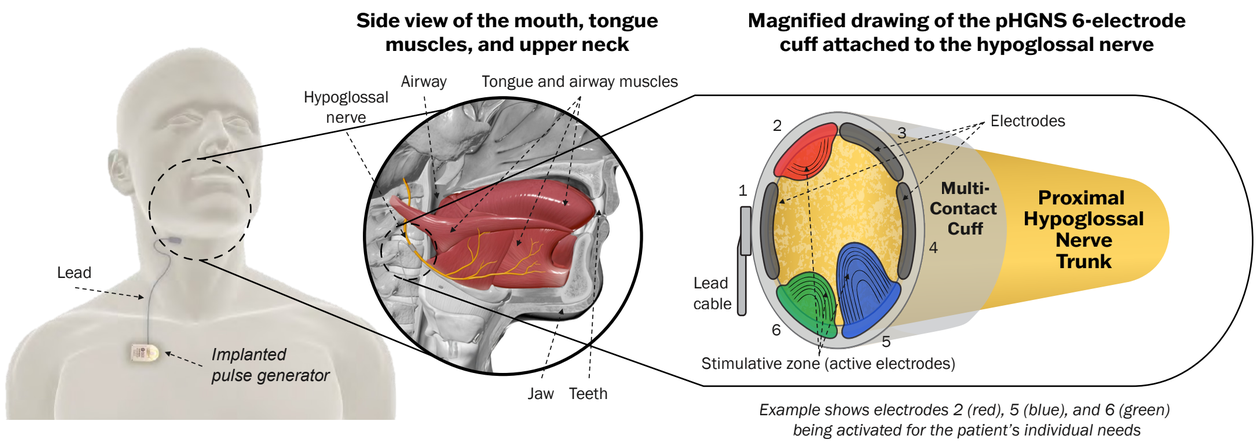
**Early treatments:** CPAP and weight loss drugs (eg, GLP-1 receptor agonists)

**Failure of CPAP:** ~50% of patients

**For patients who cannot tolerate or are otherwise unable to continue CPAP, an effective and safe therapy is needed**

## What Is pHGNS?

The **hypoglossal nerve** is a motor nerve that controls tongue movement. **pHGNS** is a medical device to treat OSA containing an electrode cuff with 6 contacts that stimulate the proximal hypoglossal nerve, leading to **tongue and airway muscle toning and stiffening to open the airway during sleep.** The **6 contacts of the electrode cuff** can be activated both individually and simultaneously, which results in a unique combination of technology and physiology and **tailoring of therapy for patient needs.**



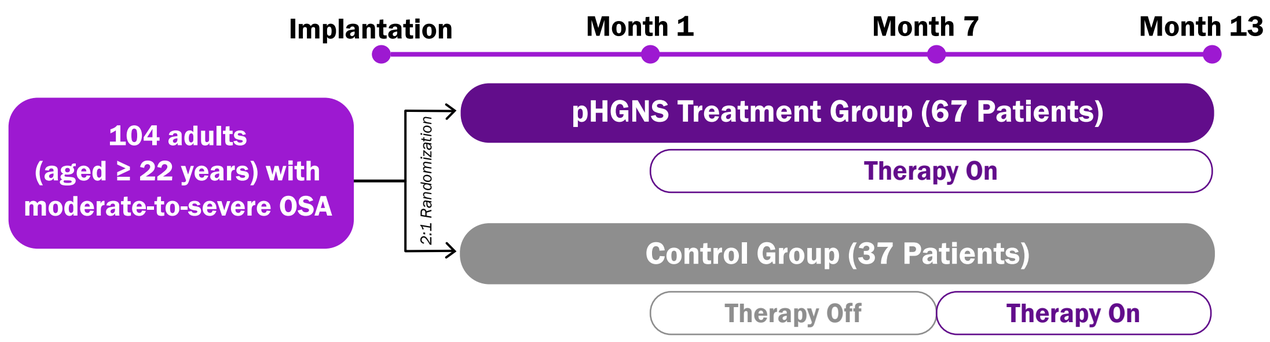

*Example shows electrodes 2 (red), 5 (blue), and 6 (green) being activated for the patient's individual needs*

## Study Objective

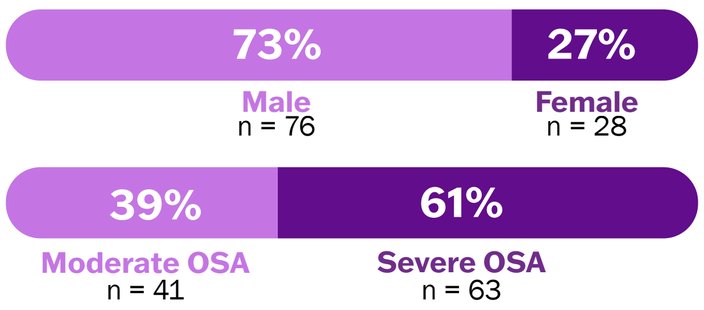
**To measure the efficacy and safety of pHGNS in adults with moderate-to-severe OSA**

## Study Design

The OSPREY study compared sleep measures and oxygen levels between 2 groups of patients: one group had pHGNS turned on ~1 month after implantation, and the other group (control → treatment) at ~7 months after implantation. Patients with complete concentric collapse (CCC) were not excluded and drug-induced sleep endoscopy was not required.




## Patients




**55.6** years — Mean age

**30.6** kg/m² — Mean BMI (> 30 = obese)

**38%** — Patients with BMI ≥ 32

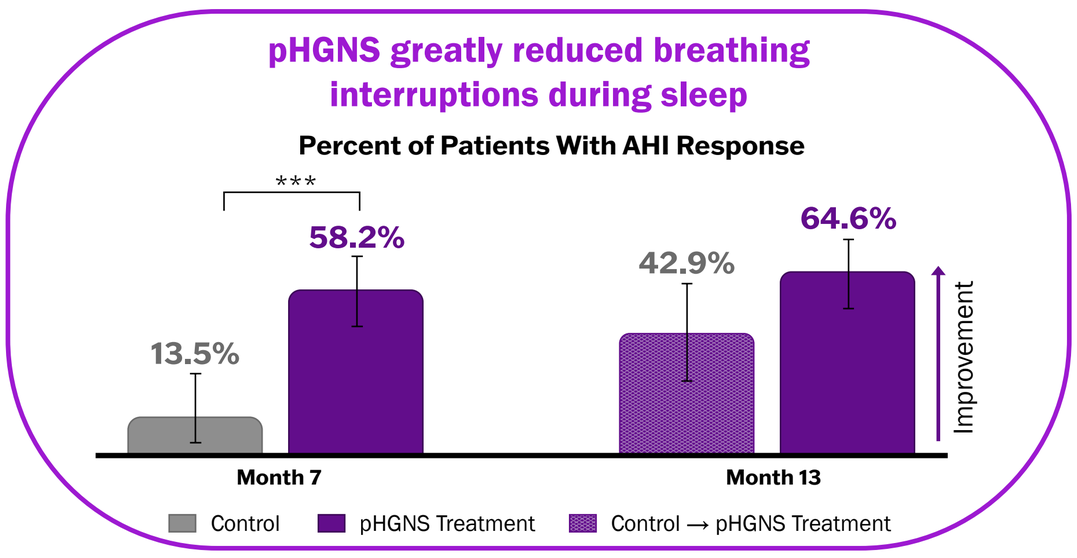
**35.7** — Mean AHI (> 30 = severe OSA)

**45%** — Patients at high risk of CCC[a]

**10.1** — Mean ESS (> 10 = excessive daytime sleepiness)

## Efficacy

### pHGNS greatly reduced breathing interruptions during sleep




AHI = number of times breathing slows or stops each hour during sleep. AHI response was defined as ≥ 50% reduction in AHI from the start of the study and AHI < 20 events/hour. ****P* < .001.

At month 7, more patients in the **pHGNS group had improved symptoms** according to their clinician's assessment and experienced **fewer drops in blood oxygen levels during sleep** than the control group.

| Percent of patients at month 7 achieving: | Control | pHGNS Treatment |
|---|---|---|
| **CGI-I response** (much or very much improved) | 8.6% | **56.3%** |
| **ODI response** (fewer drops in blood oxygen levels) | 37.8% | **68.7%** |

CGI-I = how much a patient's illness has improved from the start of the study. ODI = drops in blood oxygen levels during breathing interruptions while asleep. ODI response was defined as ≥ 25% improvement in ODI from the start of the study.

**Daytime sleepiness** (ESS) and other **patient-reported sleepiness symptoms** (FOSQ, PROMIS-SDI, and PROMIS-SRI) **improved at month 7 with pHGNS treatment**

**At month 13, improvements in all outcome measures at month 7 were maintained in the pHGNS group; patients who switched from the control group to the treatment group experienced substantial improvements in OSA symptoms and sleepiness**

## Safety

**Most common side effects** (> 10% of patients in the pHGNS treatment group) were **Headache** | **Implant site pain** | **Difficulty swallowing**

**0** **serious side effects** related to the device or implantation procedure

Most side effects were **mild or moderate** in severity

[a]Data on file, LivaNova PLC. Based on the recently presented PREDICTOR algorithm (Weiner J. Presented at the 2024 International Surgical Sleep Society Educational Update, September 27, 2024, Miami, FL. https://surgicalsleep.org/wp-content/uploads/2025/11/16253-ISSS-2024-EducationI-Agenda-22.pdf).