

Clinical Trial of the Cryosa System for the Treatment of Obstructive Sleep Apnea

NCT06008626

Status	RECRUITING
Phase	Not Applicable
Sponsor	Cryosa, Inc.
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (6)

- Age 22 - 70 years
 - Not able to use, refuse to use or intolerant of Positive Airway Pressure (PAP) or Mandibular Advancement Device (MAD) if using, must be ≤ 4 hours per night, ≤ 5 days/week.
 - Failed, are not candidates for, or have refused other invasive procedures such as hypoglossal nerve stimulation or pharmacotherapy for the primary treatment of OSA such as Tirzepatide.
 - BMI ≤ 30 or ≤ 40 kg/m² at enrollment
 - AHI ≤ 30 at enrollment based on in-lab polysomnography study OR AHI ≤ 15 and BMI of ≤ 30 at enrollment based on in-lab polysomnography study Is geographically stable and in close proximity to the site
- ... and 1 more (see full listing online)

Exclusion (36)

- Contraindication to general anesthesia or in the opinion of the Investigator would not be able to tolerate the procedure, including intubation during the procedure or in response to an adverse event
 - Actively taking ACEs/ARBs
 - Actively undergoing immunotherapy (Allergy shots)*, or unwilling to washout of allergy shots at least 2 weeks prior to study procedure.
 - * Patients receiving immunotherapy may be eligible if they undergo a 2-week wash-out prior to the study procedure
 - Severe uncontrolled asthma
- ... and 31 more (see full listing online)

Locations (8 total)

UCHealth University of Colorado, Aurora, Colorado, United States
University of Miami, Miami, Florida, United States
Rush University Medical Center, Chicago, Illinois, United States
... and 5 more locations

<https://clinicaltrials.gov/study/NCT06008626>

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