

Inspire UAS High Apnea Hypopnea Index (AHI)/High Body Mass Index (BMI) Post-Approval Study

NCT07113288

Status RECRUITING
Sponsor Inspire Medical Systems, Inc.
Enrollment 70 participants

Key Eligibility Criteria

Inclusion (6)

- Subject is at least 18 years of age;
 - Subject has a diagnosis of severe OSA (65 d AHI d 100) based on a recent sleep study (within 12 months) OR Subject has a diagnosis of moderate to severe OSA (15dAHI d 100) AND a baseline Body Mass Index of $32 < BMI < 40$ kg/m²;
 - Subject has documented failure of, or intolerance to, positive airway pressure treatments (such as CPAP or BPAP machines; NOTE: PAP failure is defined as an inability to eliminate OSA (AHI > 15 despite PAP usage). PAP intolerance is defined as the inability to use PAP (> 5 nights per week, 4 hours of usage per night) or unwillingness to use PAP (e.g. patient returns the PAP system after attempting to use it).
 - Subject is willing and able to have stimulation hardware permanently implanted and to use the patient remote to activate the stimulation;
 - Subject is willing and able to return for follow-up visits, undergo sleep studies (including in-lab and at-home), and complete questionnaires related to the study;
- ... and 1 more (see full listing online)

Exclusion (8)

- Subject has a combination of central + mixed apneas $> 25\%$ of the total apnea-hypopnea index (AHI) based on a recent sleep study (within 12 months);
 - Subject has any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate;
 - Subject has any condition or procedure that has compromised neurological control of the upper airway;
 - Subject is unable or does not have the necessary assistance to operate the patient remote;
 - Subject is pregnant or plans to become pregnant;
- ... and 3 more (see full listing online)

Locations (5 total)

Colorado ENT & Allergy, Colorado Springs, Colorado, United States
Florida Sleep Specialists, Bradenton, Florida, United States
Rush University Medical Center, Chicago, Illinois, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT07113288>

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