

Maridebart Cafraglutide Versus Placebo in Adult Participants With Obstructive Sleep Apnea on Positive Airway Pressure Therapy

NCT07225686

Status	RECRUITING
Phase	Phase 3
Sponsor	Amgen
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (4)

- AHI \leq 15 on polysomnography at day 1 before randomization.
- BMI \leq 27 kg/m² at screening.
- History of at least 1 unsuccessful attempt at weight loss by diet and exercise.
- On positive airway pressure (PAP) therapy for at least 3 consecutive months before screening and plan to continue PAP therapy during the trial.

Exclusion (6)

- Had any previous or planned upper airway surgery for sleep apnea or major ear, nose, or throat surgery.
 - Significant craniofacial abnormalities that may affect breathing at screening.
 - Diagnosis of Central Apnea with % of central apneas/hypopneas \geq 50%, and/or diagnosis of Cheyne Stokes Respiration.
 - Active device treatment of obstructive sleep apnea other than PAP therapy (eg, oral appliances), or other treatments, that in the opinion of the investigator, may interfere with trial outcomes, unless willing to stop treatment at screening and throughout the trial.
 - Respiratory diseases such as obesity hypoventilation syndrome or daytime hypercapnia, or neuromuscular diseases such as myasthenia gravis or other conditions that could interfere with the results of the trial in the opinion of the investigator.
- ... and 1 more (see full listing online)

Locations (37 total)

Peninsula Research Associates, Rolling Hills Estates, California, United States
Teradan Clinical Trials, Brandon, Florida, United States
Destiny Research Center, Palmetto Bay, Florida, United States
... and 34 more locations