Contact Information

For more information on this clinical research study or to see if you may qualify to participate, please contact the study team at:

Phone Number

480-747-3547

E-mail Address

Research@sleeplessinarizona.com

Our Location

8330 E. Hartford Dr., Suite 100
Scottsdale, AZ 85255

What is the Vivo NOVA study?

The goal of the Vivo NOVA study is to evaluate the safety and effectiveness of the auto-EPAP feature on the Vivo 45 LS Ventilator.

The Vivo 45 LS ventilator can help keep the airways open during sleep while providing respiratory support to patients diagnosed with e.g. obesity hypoventilation syndrome (OHS), chronic obstructive pulmonary disease (COPD), or neuromuscular disease (DMD, ALS).

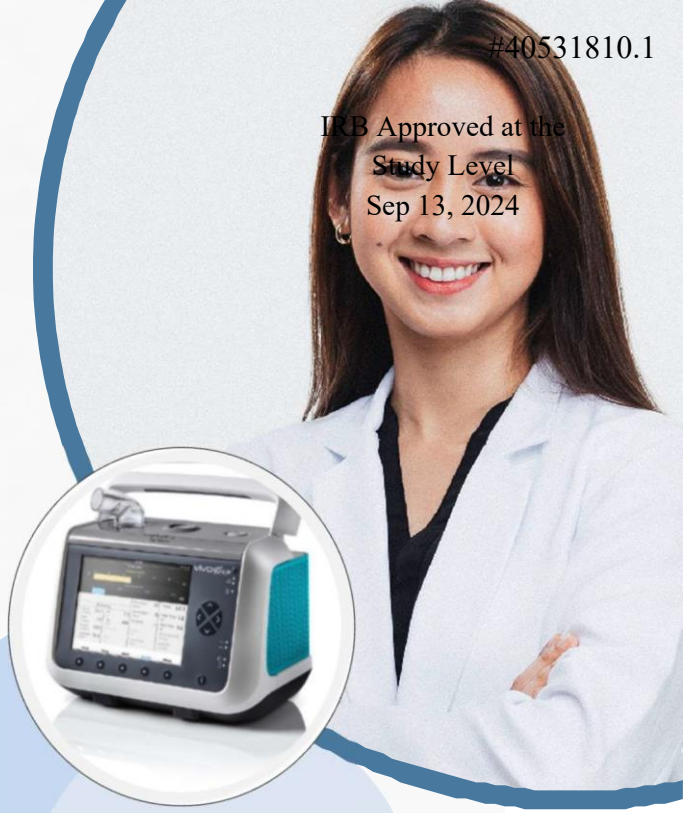
The research team will observe and document data from the sleep lab to determine if the auto-EPAP feature performs similarly to manual- EPAP in preventing a drop in blood oxygen levels during an overnight PSG assessment.

Approximately 20 participants may be enrolled in this study.

BREAS

#40531810.1

IRB Approved at the Study Level
Sep 13, 2024



Breas Medical, Inc.

Vivo NOVA Study

Are You Eligible?

- 18 years or older
- Diagnosis of chronic respiratory insufficiency or failure due to:
  - Chronic Obstructive Pulmonary Disease (COPD)
  - Obesity Hypoventilation Syndrome (OHS)
  - Neuromuscular Disease (NMD)
- Co-existing Obstructive Sleep Apnea (OSA)
- Qualifying diagnostic PSG resulting in AHI at least 5 per hour
- Using non-invasive ventilation (NIV) during sleep for at least 3 months
- EPAP settings have been reviewed in the last 12 months
- Can tolerate at least 4 hours of NIV use

What Will Happen During the Study?

- Participation in this study will last approximately 5 weeks.
- If you decide to take part in this research study, the general procedures include collecting information about your medical history and medications, and review of data from your current ventilator or BiPAP device.
- Once eligibility is confirmed, you will participate in two separate overnight stays at a sleep lab where a polysomnography (PSG sleep study) will be performed. During the PSG you will be using the Vivo 45 LS fitted with your own face mask, if possible.

Planned Study Visits

Visit 1: Screening Visit
Medical history, Physical exam, Medications, and Data Review from your ventilator or BiPAP device

Visit 2: Overnight PSG - Night 1
Within 30 Days of Screening Visit

Visit 3: Overnight PSG - Night 2
Within 4 to 7 Days of the Overnight PSG - Night 1

Volunteer Participation

This is a research study and your participation is voluntary.

The alternative to taking part in this study is to not take part in this study. If you choose not to participate, this will not impact any care that you currently receive. Please talk to your Investigator about your choices before deciding if you will take part in this study.

Risks

The identified risks for using the Vivo 45 LS ventilator are similar to the risks for using your currently prescribed ventilator or BiPAP device. The potential complications associated with a sleep study are minor and include irritation/reaction to the adhesives used to attach the sensors, difficulty falling asleep and/or poor sleep leading to drowsiness. All known risks will be discussed before you decide if you would like to participate in the study.