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IRB Approved at the
Study Level
Jul 26, 2024

Paid Volunteers Needed for Participation in Research Sleep Study

What is the Vivo NOVA Study?

The goal of the Vivo NOVA study is to confirm the safety and effectiveness of the auto-EPAP feature on the Vivo 45 LS Ventilator. The Vivo 45 LS Ventilator is used to keep the upper airways open during sleep, while providing respiratory support to patients diagnosed with e.g. COPD, OHS or NMD.

During an overnight PSG study in the sleep lab, a research team will observe and document data to determine if the auto-EPAP feature in the Vivo 45 LS ventilator performs similarly to manual EPAP in preventing a drop in blood oxygen levels during sleep.

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 currently used 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.
- Participants will receive compensation and are eligible for travel reimbursement.

Location

All study visits will be in *Columbia, SC*

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)
  - With Co-Existing Obstructive Sleep Apnea
- Qualifying diagnostic PSG resulting in AHI at least 5 per hour (untreated)
- Currently using non-invasive ventilation (NIV) during sleep for the at least 3 months
- EPAP settings have been reviewed in the last 12 months
- Can tolerate at least 4 hours of NIV use

Contact Information

- The principal investigator at this site is *Richard Bogan, MD*
- If you are interested in learning more about the study, please call or email a member of the study team:

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Study Sponsored by:

BREAS

Recruitment Flyer v2.0 26-Jun-2024