STIMIT Activator 1 IDE Study

NCT05883163

Status	RECRUITING
Phase	Not Applicable
Sponsor	Stimit AG
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (3)

- Are 21 years or older, and,
- Have recently been placed on invasive MV (enroll and randomized as soon as possible after intubation), and have received no more than 7 days of MV
- Are predicted to remain on mechanical ventilation for an additional 48 hours or longer post randomization

Exclusion (14)

- Patients that are actively treated with continuous infusion of neuromuscular blocking agents beyond the enrollment period.
- Medical condition known to affect the phrenic nerve or respiratory muscles (examples of possible medical conditions that could affect the phrenic nerve provided in Annex 1 below).
- Any patients with ICP probe.
- Patients with metallic device implants or body penetrating metallic devices in the upper body area within 30cm (12inches) from the coils; known anatomy or devices in the neck area (e.g., ECMO cannulas in the neck area, collars or cranial appliances) that would interfere with headset placement or stimulation.
- Any non-removable electrical / electronic device (device internal or external) that may be prone to interaction with, or interference from the STIMIT Activator, such as pacemakers, implantable defibrillators, implanted medication pumps, bio-stimulators, deep brain stimulators, implanted nerve stimulator, deep brain stimulators or cochlear device implants.

... and 9 more (see full listing online)

Locations (4 total)

Yale New Haven Hospital, New Haven, Connecticut, United States
Beth Israel Deaconess Medical Center, Boston, Massachusetts, United States
University of Virginia Medical Center, Charlottesville, Virginia, United States
... and 1 more locations

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