PACIFIC NEUROSCIENCE INSTITUTE℠

JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

Pivotal Randomized Clinical Trial of Peripheral Nerve Stimulation with StimRouter Neuromodulation System in Overactive Bladder

Official Title: Propspective, Multi-Center, Randomized, Double-blinded, Partial Crossover Trial of Percutaneous Tibial Nerve Stimulation with the Bioness Stimulator with the Bioness Stimrouter Neuromodulation System versus Sham in the Treatment of the Overactive Bladder (OAB)

Overactive bladder (OAB) syndrome affects nearly 17% of the population. Symptoms include urgency to void, incontinence, abnormal voiding frequency, and nocturia. These symptoms have the potential to affect the quality of life, cause social isolation, trigger depression, and result in an increased incidence of falls and fractures. Standard lines of clinical treatment include behavioral therapies, anti-muscarinic agents, adrenergic receptor agonists, or invasive treatments such as Botox, sacral neuromodulation, and percutaneous tibial nerve stimulaiton. These come with side-effects which can be intolerable or diminished over the long term.

The StimRouter has been FDA approved in adults with chronic pain of peripheral nerve origin and has shown a significant decrease in pain with no severe adverse events related to the device. The purpose of this study is to assess the efficacy of the StimRouter stimulation therapy in improving OAB symptoms of urgency and frequency as measured by Patient Voiding Diary when targeting the posterior tibial nerve.

Key Inclusion Criteria:

- Age ≥ 22 years
- Minimum 3 months of self-reported OAB symptoms
- Average urinary frequency of ≥ 10 daily voids associated with urgency
- Failed /inadequate response to first- and second-line therapy for OAB

Key Exclusion Criteria:

- Treatment of bladder or pelvic floor dysfunction with botulinum toxin (Botox®) or surgery in past 12 months
- Neurogenic bladder
- Type 1 Diabetes or Uncontrolled Type II Diabetes

For more information, contact the Neurosciences Clinical Trial Team at:
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