NM019

A PROSPECTIVE SHAM-CONTROLLED SAFETY AND EFFICACY TRIAL OF A WEARABLE TRANSCUTANEOUS TIBIAL NEUROMODULATION SYSTEM TREATING OVERACTIVE BLADDER SYNDROME (REDUCEOAB)

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Introduction and Objective

OAB patients face treatment challenges often attributed to high cost, adverse effects, and apprehension towards invasive therapy. The Vivally System is a non-invasive, wearable transcutaneous tibial neuromodulation therapy and mobile app system that avoids risks associated with surgical implants and drug side effects. Integrated EMG is used to create a "closed-loop" system that continuously adjusts therapy based on feedback. This multicenter, sham-controlled study aimed to establish the safety, efficacy, and usability of the system for treatment of OAB symptoms.

Methods

This was a randomized, sham-controlled, double-blind, multi-center study conducted on subjects using the Vivally System for OAB symptoms. Participants were randomized to either active or sham arms. Treatment duration spanned 12 weeks, with data gathered from a 3-day bladder diary. Primary endpoints included responder rates for urgency, leaks, and voiding frequency at week 12. Secondary endpoints included incontinence, urgency, voids, and symptom improvement metrics. Quality of Life (QoL) was gauged using validated tools such as OAB-q, I-QoL, and OABSS. Therapy adherence, device safety, and system usability were tracked.

Figure 1: Vivally System garment placed on foot/ankle with mobile app

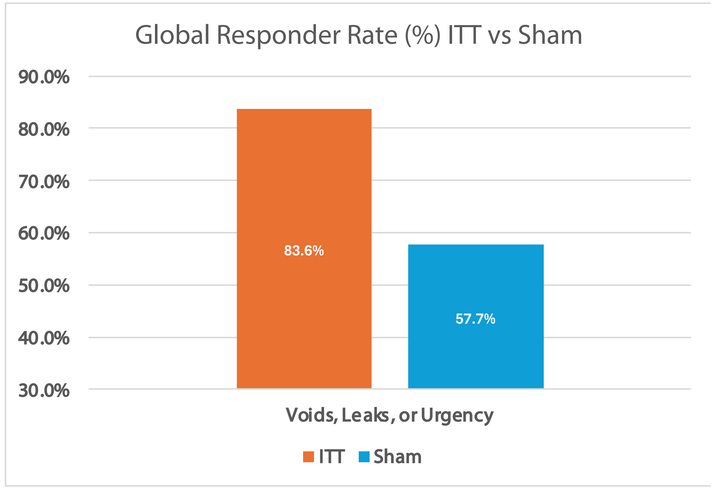

Figure 2: Global Responder Rate (%) ITT vs Sham

Results

Of 211 screened subjects, 125 (59.2%) were randomized, with 112 (89.6%) completing the 12-week follow-up. The demographics were predominantly female (121, 96.8%) with a mean age of 62.7 ± 11.77 years. Baseline symptoms were comparable between groups. The ITT global responder rate for voids, leaks, and urgency was significantly higher in the treatment (83.6% [73.8-93.4]) versus sham (57.7% [44.3-71.1], p=0.032). Respective incontinence and void responder rates in the ITT were 71.8% [57.7-85.9] vs. 59.5% [43.7-75.3] and 57.1% [43.2-71.0] vs. 40.5% [25.7-55.3]. The mean OAB-q QoL score change from baseline to 12 weeks was 19.01 ± 19.81 in treatment and 16.14 ± 18.89 in sham. Overall satisfaction and system usability were rated highly: 98.9% were satisfied and found the system easy, while 95.6% expressed willingness to continue using for their OAB.

Conclusion

The Vivally System, a non-invasive, wearable transcutaneous tibial neuromodulation therapy and mobile app system, demonstrates significant effectiveness in reducing OAB symptoms compared to sham. With high patient satisfaction, ease of use, and willingness to continue treatment, it offers a promising alternative for patients seeking convenient and non-invasive management for OAB.

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