Title	Nerve stimulation's effectiveness at UI frequency in overactive patients in home
NCT#	NCT03595215
Objectives	To demonstrate safety and effectiveness of nerve stimulation using the Leo-U TranStim System
Indications for Use/Patient Population	Leo-U TranStim System is intended for use in patients suffering overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence (UI). Subjects will receive treatment sessions of Nerve Stimulation each week for 8 weeks, at home.
Trial Design	Single center feasibility, non-randomized, unblinded, Non-Significant Risk (NSR) trial.
Number of Subjects	11
Number of Sites	1
Inclusion Criteria	Candidates must meet ALL of the following: 1. Females 2. 55-100 years old 3. Have an average urinary frequency of ≥ 8 voids per 24 hours (based on a pre-treatment 3-day voiding "training" diary) 4. Have self-reported bladder symptoms of more than 3 months 5. Are ambulatory and able to use the toilet independently 6. Have been off antimuscarinics, anticholinergics or beta-3 agonists for at least 2 weeks prior to enrollment OR on a stable dose for the prior 3 months 7. Patient has urinary urge incontinence of ≥ 8 episodes from a 3-day diary (with incontinence associated at urge level moderate or severe) 8. Able to provide informed consent 9. Capable and willing to follow all study-related procedures
Exclusion Criteria	Candidates cannot meet ANY of the following: 1. Have primary complaint of stress urinary incontinence 2. Have a pacemaker or implantable defibrillator 3. Had botox injections in the bladder or pelvic floor muscles in the past 12 months 4. Have a current urinary tract or vaginal infection 5. Have an active implantable SNS device (InterStim & Bion) 6. Have been diagnosed with peripheral neuropathy or nerve damage 7. Currently pregnant 8. Deemed unsuitable for enrollment in study by the investigator based on subjects' history or physical examination

Procedures	1. Subjects will sign the Informed Consent and be screened for eligibility in the study. Subjects will receive receive the voiding diaries and questionnaires, which will be completed at home. 2. Subjects will complete "training" voiding diary. 3. Subjects will complete another 3-day voiding diary and an OAB-q to establish a baseline. 4. Once questionnaires are complete, subjects will visit the site, and receive instructions on how to use the TranStim device. 5. Subjects will bring the TranStim device with them for in-home use. For 8 weeks, subjects will self-administer minutes of TranStim therapy. The patient will fill out voiding diary and an OAB-q at the start of their 5th and 8th week of treatment. 6. Subjects will return to the clinic at the after their 8th treatment week to determine if there are any SAEs or UADEs. Subjects will return study related materials to the site during this last visit.
Endpoints	**Efficacy Endpoints** (following Leo-U TranStim therapy)**:** 1. At least 50% decrease in the number of UI episodes compared to pre-treatment 2. At least 20% decrease in micturitions per day compared to pre-treatment 3. At least 15% improvement in incontinence QoL scores compared to pre-treatment **Primary Safety Endpoint** The incidence and severity of Adverse Events (AEs) including device and procedure-related AEs. The incidence and severity of SAEs (regardless of relationship to device or procedure). Primary safety endpoints will be evaluated at follow-up visit.
Safety	Adverse Events (both expected and unexpected) will be recorded and reported appropriately throughout the study.
Sample Size Calculation	This is an open-label feasibility study with the goal of providing proof of-principle data for TranStim. Therefore, we will be evaluating the results for trends that support further investigation. Nonetheless, by having each subject serve as her own control, using a repeated measures ANOVA, a sample size of 10 will provide sufficient power to detect an effect size of 0.7 (α=0.05, power=0.80). Eleven subjects will be enrolled to account for a 10% drop-out rate.