

Study of 30-Minute Stimulation With the Neuspera Sacral Neuromodulation (SNM) System

NCT07247136

Status	RECRUITING
Phase	Not Applicable
Sponsor	Neuspera Medical, Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (6)

- Is male or female 22 years of age or older.
- Has a diagnosis of UUI for greater than or equal to 6 months prior to the screening baseline visit date.
- Has failed, could not tolerate (stopped taking medication due to lack of efficacy or intolerable side effects), or not a good candidate for (as determined by treating physician) at least one (1) antimuscarinic or α 3adrenoceptor agonist medication.
- Is willing and able to washout (at least five half-lives) from OAB medications for a period determined appropriate based on type of OAB medication prior to the baseline bladder diary and remain off OAB medications through the study duration OR must be willing to maintain medication through the study duration.
- Has a diagnosis of UUI with at least 4 UUI episodes on a 72-hour diary.

... and 1 more (see full listing online)

Exclusion (18)

- Has a contraindication for the Neuspera SNM System per the device labeling.
- Has a hemoglobin A1c of $\geq 8\%$.
- Has glucosuria.
- Has diabetic neuropathy.
- Has interstitial cystitis or bladder pain syndrome as defined by either American Urological Association (AUA) or European Association of Urology (EAU) guidelines, chronic pelvic pain, or recurrent symptomatic urinary tract infections.

... and 13 more (see full listing online)

Locations (1 total)

Southern Urogynecology, LLC, West Columbia, South Carolina, United States