PMCF Study of the Axonics SNM System Model 5101 (R20)

NCT06789406

Status	RECRUITING
Phase	Not Applicable
Sponsor	Axonics, Inc.
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (3)

- years or older
- Primary indication of OAB (urinary urgency incontinence (UUI) / urinary frequency (UF) who are not candidates for, or who have failed conservative treatment
- Willing and capable to provide written consent and agrees to comply with specified evaluations at clinical centers for all follow-up assessments

Exclusion (6)

- Any significant medical condition that is likely to interfere with procedures, device operation, or likely to confound evaluation of endpoints (i.e., neurological conditions such as multiple sclerosis)
- Any psychiatric or personality disorder that is likely to interfere with procedures at the discretion of the participating physician; this may include poor understanding or compliance with requirements
- Previously underwent an external sacral neuromodulation SNM trial and was deemed a non-responder or was previously implanted with a sacral neuromodulation device and did not get therapeutic benefit (a non-responder)
- History of allergic response to titanium, zirconia, polyurethane, epoxy, or silicone
- A female who is breastfeeding

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

Locations (4 total)

University of Chicago, Chicago, Illinois, United States
Bradford Royal Infirmary, Bradford, West Yorkshire, United Kingdom
Pinderfields Hospital, Wakefield, West Yorkshire, United Kingdom
... and 1 more locations