

Pelvic Health Electrically Evoked Recording (PEER) 2 Study

NCT05200923

Status	RECRUITING
Phase	Not Applicable
Sponsor	MedtronicNeuro
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (22)

- years of age or older
- Candidate for or undergoing Medtronic InterStim lead implant for labeled indication* requiring an advanced evaluation
- Willing and able to provide signed and dated informed consent
- Willing and able to independently and accurately complete diaries, questionnaires, attend visits, and comply with the study protocol
- Willing to maintain current regimen (dosage and frequency) of any OAB medication from baseline diary through the end of therapy evaluation

... and 17 more (see full listing online)

Exclusion (36)

- Currently enrolled or planning to enroll in an interventional clinical study that could potentially confound the study results (co-enrollment in an interventional study is only allowed when documented pre-approval is obtained from the Medtronic study manager or designee)
- Implanted with a neurostimulator, pacemaker or defibrillator
- Pelvic floor muscle dysfunction due to surgical intervention or injury
- Have neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy or spinal cord injury (e.g., paraplegia)
- History of diabetes unless the diabetes is well-controlled through diet and/or medications

... and 31 more (see full listing online)

Locations (7 total)

Indiana University Health Methodist Research Institute, Indianapolis, Indiana, United States

LSUHSC Department of Urology, New Orleans, Louisiana, United States

Ochsner Clinic Foundation, New Orleans, Louisiana, United States

... and 4 more locations