

BTL Emsella Chair Versus Sham for the Treatment of Stress Urinary Incontinence

NCT04133675

Status	RECRUITING
Phase	Not Applicable
Sponsor	Corewell Health East
Enrollment	110 participants

Key Eligibility Criteria

Inclusion (10)

- Able to read, understand, and provide written, dated, informed consent prior to screening, and be likely to comply with study protocol, including independently complete study questionnaires and communicate with study personnel about AEs and other clinically important information.
- Females and males, 18 to 80 years of age, inclusive, at screening
- Positive Cough or Bladder Stress Test at screening
- Subject agrees not to start any new treatment (medication or otherwise) during the treatment and follow-up periods.
- \. Subject agrees to maintain a stable dose of any medication known to affect lower urinary tract function, including but not limited to anticholinergics, tricyclic antidepressants, beta-3 adrenergic agonist, or ~~ad~~adrenergic blockers, throughout the treatment and follow-up periods.

... and 5 more (see full listing online)

Exclusion (22)

- Pelvic floor physical therapy, including muscle training and/or electrostimulation, in a clinical setting within 30 days prior to screening
- Subject is morbidly obese (defined as body mass index 40 or greater)
- Pulmonary insufficiency, defined as difficulty breathing and fatigue, especially during exercise; chest pain, such as squeezing, pressure or tightness; the sensation of rapid or irregular heartbeat (palpitations); swelling of the legs or feet; dizziness or fainting; and/or bluish discoloration of the nails and/or lips (cyanosis)
- Any condition that causes a lack of normal skin sensation to the pelvis, buttocks, and lower extremities
- Implanted cardiac pacemaker or metal in the body, including, but not limited to drug pumps, neurostimulators, electronic implants, copper intrauterine devices (IUDs), and/or defibrillators

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

Locations (1 total)

Corewell Health William Beaumont University Hospital, Royal Oak, Michigan, United States

<https://clinicaltrials.gov/study/NCT04133675>

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