Male patients with non-neurogenic OAB needed for clinical investigation with the Neurostimulation Device (UCon)

Title: Safety and Performance of UCon for Management of Non-Neurogenic OAB In Males – An Early Feasibility Study

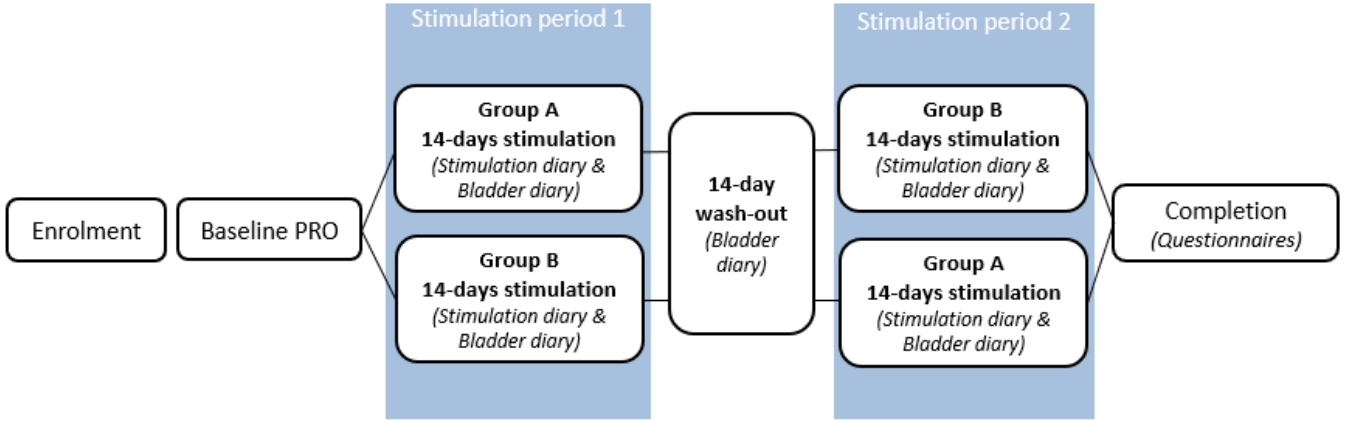
Aim: To evaluate UCon (medical device) with respect to initial clinical safety and device performance.

Design: Randomized, cross-over, single-site, prospective, early feasibility study.

Subjects: 20 males *(see criteria)*

Intervention: The subjects are randomized into two groups for a cross-over setup. Both groups receive dorsal genital nerve (DGN) stimulation with two different stimulation modes for the two stimulation periods.

Nature and extent of burden: The individual subject must *(not all shown on the study flow):*
- Visit the MUMC+ 5-6 times over a period of approx. 7 weeks
- Apply electrical stimulation for a minimum of 28 days
- Complete 3-days bladder diaries *(4 times)*
- Complete stimulation diaries *(5 times)*
- Complete complications diaries *(2 times)*
- Complete device and treatment satisfaction surveys *(2 times)*
- Complete QoL Questionnaires *(3 times)*



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Inclusion criteria

1. Subject is **≥ 18 years of age**.
2. Subject is **male**.
3. Subject is diagnosed with **OAB**
4. Subject is able to communicate, provide feedback, understand and follow instructions during the course of the investigation.

Exclusion criteria

1. Subject is medically unstable (acute illness or complications of a chronic condition)
2. Subject has a PVR > 100 ml or a BVE <75% (measured by uroflowmetry as the ratio of voided volume and total bladder capacity.
3. Subject has an active infection in the genital area incl. skin infections and UTI.
4. Subject has had botulinum toxin (BOTOX) treatment in the pelvic region within 6 months.
5. Subject has used antimuscarinics or β3 agonists within 14 days weeks*.
6. Subject has an implanted pacemaker, implantable drug pump or other active medical device (any medical device that uses electrical energy or other power source).
7. Subject is enrolled or planning to enroll in another clinical investigation or was enrolled in an investigational drug study or medical device investigation within four weeks to enrolment.
8. Subject has neuropathy to a degree that is presumed to diminish the effect of the electrical stimulation.
9. Subject has a history of cancer in the pelvic region, are currently receiving cancer treatment, or has radiation-induced damage to the pelvic region.
10. Subject has addictive behavior defined as abuse of alcohol, cannabis, opioids, or other intoxicating drugs.
11. Subject does not speak or understand Dutch.