InterStim Amplitude Study

Published: 06-09-2018
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The primary objective in the study is to explore the effect of three different amplitude setting s (50% of sensory threshold, 80% of sensory threshold and sensory threshold) on number of UUI episodes per day.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON46694

Source
ToetsingOnline

Brief title
InterStim Amplitude Study

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Over active bladder, urinary urge incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: InterStim II system, overactive bladder (OAB)., urinary urge incontinence (UUI).

Outcome measures

Primary outcome

The primary objective in the study is to explore the effect of three different a

mplitude settings (50% of

sensory threshold, 80% of sensory threshold and sensory threshold) on number of

UUI episodes per day

Secondary outcome

Secondary objective of this study is quality of life (ICIQ*

OABqol) for the three different amplitude settings.

Additional measures include: *

Safety *

Patient Global Impression of Improvement (PGI*I) *

Urinary Frequency

Study description

Background summary

One of the most common patient complaints about sacral neuromodulation (SNM) for overactive bladder (OAB) is unwanted or uncomfortable stimulation. It is often assumed that higher amplitude
stimulation will provide better efficacy, but there is a lack of clinical eviden
ce regarding amplitude effects of SNM for OAB. However, there is some evidence t
hat SNM for fecal incontinence is effective at sub-sensory threshold/
amplitude.This study will explore whether lower amplitude stimulation can
provide improved symptom control when compared to baseline. Potential effects
of lower amplitude
may include changes in or sustained efficacy, or reduced patient complaints due
to uncomfortable stimulation.

More information can be found under Section 4; Background CIP page 17 of the protocol

Study objective

The primary objective in the study is to explore the effect of three different a mplitude settings (50% of sensory threshold, 80% of sensory threshold and sensor y threshold) on number of UUI episodes per day.

Study design

This is a prospective, randomized, multicenter, single*blinded study to explore the efficacy and quality of life (QoL) of 3 different amplitude settings. The study will be conducted at approximately 20 centers in the United States, Canada and Europe.
Enrolled subjects who meet all eligibility criteria, have successful therapy evaluation (50% improvement in UUI or UF voiding symptoms, or return to normal voiding of < 8 voids per day for UF subjects) and qualify for a neurostimulator device implant in the study will be randomized to one of the 3 amplitude settings. Subjects will complete enrollment/baseline visits, lead implant, therapy evaluation, neurostimulator device implant, randomization, 1*week follow*up visit, 6* week follow*up visit and 12*week follow*up visit.
The total study duration for a subject is approximately 16 weeks.

Intervention

1. Enrollment / Baseline
2. Tined Lead or temporary Test Stimulation Lead Implant
3. Therapy Evaluation
4. Neurostimulator Device Implant (randomization procedures)
5. One Week Follow*up Visit
6. Six Week Follow*up Visit
7. Twelve Week Follow*up Visit

See Protocol pages 22 until 28 .

Study burden and risks

Participation in this study will not expose the subject to greater risks than if he/she were receiving
InterStim Therapy outside of the study. There might be other discomforts and ris ks related to InterStim Therapy and/
or this study that are not foreseen at this time. In addition, based on the amp litude
settings, subjects may experience less than desired improvements in OAB symptoms .

The risks associated with InterStim II System are minimized in this study by sel
ecting only qualified
Investigators experienced in InterStim Therapy, selecting an appropriate patient
 population via
inclusion/exclusion screening, and monitoring subject progress and events report
ed for this study. The
review and minimization of the potential risks to the patient and the potential
benefits to the patient support the conduct of this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Primary diagnosis of urinary urge incontinence (UUI) as demonstrated on a 3-day baseline voiding diary demonstrating at least 3 UUI episodes

2. Female subjects 18 years of age or older
3. Candidate for InterStim Lead Placement
4. Willing and able to accurately complete voiding diaries, questionnaires, attend visits, and comply with the study protocol (which includes maintenance of InterStim II programming settings over the course of the study)
5. Willing and able to provide signed and dated informed consent
6. Willing to maintain current regimen (dosage and frequency) of any overactive bladder (OAB) medication

Exclusion criteria

1. Have neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy or spinal cord injury
2. History of diabetes unless the diabetes is well-controlled through diet and/or medications
3. Symptomatic urinary tract infection (UTI)
4. Have primary stress incontinence or mixed incontinence where the stress component overrides the urge component
5. Treatment of urinary symptoms with botulinum toxin in the past 9 months or any plan to have botulinum toxin treatment during the study
6. Implanted with a neurostimulator, pacemaker, or defibrillator
7. Have knowledge of planned MRIs, diathermy, microwave exposure, high output ultrasonic exposure, or RF energy exposure not included within the scanning conditions provided with the MRI Guidelines for InterStim Therapy
8. Women who are pregnant or planning to become pregnant
9. Characteristics indicating a poor understanding of the study or characteristics that indicate the subject may have poor compliance with the study protocol requirements
10. Currently enrolled or planning to enroll in a potentially confounding clinical study during the course of the study (co enrollment in concurrent studies is only allowed when documented pre-approval is obtained from the Medtronic study manager (or designee)

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	InterStim II (Model 3058) and InterStim Tined Lead Model 38 89
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-09-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03335761
CCMO	NL63881.078.17