# **InterStim Amplitude Study**

Published: 06-09-2018 Last updated: 12-04-2024

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\*

OABgol) 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 risks 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**

#### **Public**

Medtronic B.V.

Endepolsdomein 5 Maastricht 6229GW NL

**Scientific** 

Medtronic B.V.

Endepolsdomein 5 Maastricht 6229GW NL

# **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

ClinicalTrials.gov CCMO ID

NCT03335761 NL63881.078.17