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Investigating the effect of different stimulation settings during sacral neuromodulation treatment for patients with detrusor overactivity and dysfunctional voiding

Submission date
26/09/2024

Recruitment status
No longer recruiting

Registration date
08/11/2024

Overall study status
Completed

Last Edited
16/01/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sacral neuromodulation (SNM) is a relatively new treatment for patients with overactive bladders (OAB, increase urinary frequency, urgency and incontinence) and dysfunctional voiding (difficulty emptying the bladder secondary to a non-relaxing urinary sphincter). The mechanisms of action for SNM is still not fully understood, in particular, how the same therapy (same surgical procedure and neuromodulator stimulating parameters), can treat two contrasting bladder conditions.

It is thought that both diseases (OAB and DV) result from inappropriate activity of the pudendal nerve (PN) activity which controls the external urethral sphincter with OAB and DV patients having decreased and increased PN activity respectively. Electrical stimulation of the PN aims to 'normalise' the activity to the urethral sphincter.

Currently, the frequency of the electrical stimulation is the same when treating both OAB and VD patients. However, the effect of PN stimulation, that is whether it results in excitation or relaxation of the sphincter, may be frequency dependant. We aim to assess the effects of different stimulation frequencies to determine of we can improve efficacy of SNM for patients with DO and DV.

Who can participate?
Patients diagnosed with detrusor overactivity or dysfunctional voiding during urodynamic assessment

What does the study involve? (for participants)
Undergoing a trial of sacral neuromodulation and varying the stimulation frequencies. Outcomes will be measured by urodynamic assessment, bladder diaries and patient questionnaires.

What are the possible benefits and risks of participating?
Risks:
1. Pain or discomfort during frequency change of SNM
2. Pain or discomfort when undergoing additional UDS investigations.
3. Risk of urinary tract infection due to urethral catheterisation for UDS investigations

Risk to benefit rationale:
UDS investigations are a low-risk routinely performed test. All usual precautions will be taken in order to minimise patient discomfort and ensure dignity.

Patients will have the benefit of receiving individualised objective data regarding the efficacy of their SNM trial as well as optimal SNM settings. The outcome of this trial could improve SNM therapy for all patients by optimising stimulation parameters for the various indications.

Where is the study run from?
Guy's Urology Centre (UK)

When is the study starting and how long is it expected to run for?
October 2021 to October 2026

Who is funding the study?
Medtronic (USA)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
311461

Central Portfolio Management System (CPMS)
62199

Protocol serial number
12024

Study information

Scientific Title
Single-centre pilot-study to determine the optimal sacral neuromodulation (SNM) stimulation parameters to treat idiopathic detrusor overactivity and dysfunctional voiding

Acronym
SNMLUTS

Study objectives
There will be an optimum stimulation frequency (5, 14 or 130Hz) which increases QOL score and bladder capacity, delays sensation milestones and/or reduces the amplitude of detrusor overactivity amplitude for OAB patients and improves voiding efficiency in patients with DV.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2024, London - Brighton & Sussex Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048016; brightonandsussex.rec@hra.nhs.uk), ref: 24/LO/0354

Primary study design
Observational

Study design
Single centre observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Detrusor overactivity, dysfunctional voiding

Interventions
This protocol covers a series of pilot studies. All patients will receive the SNM standard of care if involved in this study with the addition of UDS investigations at different time points (see flow chart overleaf). The purpose of this trial is to better understand the benefit of varying stimulation frequency and potentially identifying a conditional stimulation trigger signal. If these concept show promise, and is feasible, a larger trial, with appropriate sample size, will be conducted.

Participants within pilot studies 1 and 2 will undergo 1 and 3 Urodynamics procedures respectively to objectively assess the change in bladder function during the trial.

On arrival to the department the participant will be asked to empty their bladder and change into a hospital gown. Using aseptic techniques, local anaesthetic and lubrication a member of the clinical team will insert a small catheter into the bladder and another into the anus (back passage). Once the catheters are in place the participant can stand or be seated while the bladder is filled slowly, which will last approximately ten minutes. Only a small amount of fluid will enter the rectum.

During the filling phase the participant will be asked to report when they need to urinate and how this feeling progresses. When bladder capacity or urgency is reproduced the participant will void (urinate) with the catheters in place, appropriate privacy will be provided at this point. Once voided the catheters will be removed. and the patient may leave the department once changed.

Pilot 1: Patients with detrusor overactivity.
-Eligibility screening and PIS given to patient during clinical visit to Urology centre.
-Verbal consent to participate via a telephone call ~2 weeks after PIS given.
-3 day bladder diary performed (the volume and time of fluid consumed and urinated).
-Day 1: Written informed consent obtained prior to SNM lead implantation.
-Day 7-14 (one visit): Urodynamics procedure, including four bladder filling cycles at different stimulation parameters 5, 14, 40 and 130Hz.
-Day 14: End of trial, SNM system either implanted permanently or removed.

Pilot 2: Patients with detrusor overactivity.
-Eligibility screening and PIS given to patient during clinical visit to Urology centre.
-Verbal consent to participate via a telephone call ~2 weeks after PIS given.
-3 day bladder diary performed (the volume and time of fluid consumed and urinated).
-Day 1: Written informed consent obtained prior to SNM lead implantation and stimulation frequency set to 5, 14 or 130Hz.
-Day 4: 1st Urodynamics procedure and complete patient questionnaire ICIQ-OAB..
-Day 5: SNM program changed to either 5, 14 or 130Hz.
-Day 9: 2nd Urodynamics procedure and complete patient questionnaire ICIQ-OAB..
-Day 10 : SNM program changed to final program, either 5, 14 or 130Hz.
-Day 14: End of trial, 3rd Urodynamics procedure and complete patient questionnaire ICIQ-OAB, SNM system either removed or permanently implanted.
-Throughout study: a bladder diary is kept each day.

Pilot 3: Patients with dysfunctional voiding.
-Eligibility screening and PIS given to patient during clinical visit to Urology centre.
-Verbal consent to participate via a telephone call ~2 weeks after PIS given.
-3 day bladder diary performed (the volume and time of fluid consumed and urinated).
-Day 1: SNM lead implanted and stimulation frequency set to 5, 14 or 130Hz.
-Day 4: Complete patient questionnaire ICIQ-FLUTS.
-Day 5: SNM program changed to either 5, 14 or 130Hz.
-Day 9: Complete patient questionnaire ICIQ-FLUTS.
-Day 10 : SNM program changed to final program, either 5, 14 or 130Hz.
-Day 14: End of trial, complete patient questionnaire ICIQ-FLUTS, SNM system either permanently implanted or removed.
-Throughout study: a bladder diary is kept each day using the Minze HomeFlow device (which automatically records volume of urination and flow rate).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pilot 1: Bladder function measured during a urodynamic assessment between day 7 and 14 at each of the following stimulation frequencies 5, 14 and 130Hz (the assessment will include four filling phases). Parameters include: capacity (ml), compliance (ml/cmH2O), detrusor overactivity peak pressure and onset (cmH2O and ml respectively), voided volume (ml), detrusor pressure at peak flowrate, Pdet.Qmax (cmH2O), maximum flowrate, Qmax (ml/s), post void residual (ml).

Pilot 2: Bladder function parameters measured during urodynamic assessments on day 4, 9 and 14 at a different stimulation frequency (5, 14 or 130Hz). Parameters include: capacity (ml), compliance (ml/cmH2O), detrusor overactivity peak pressure and onset (cmH2O and ml respectively), voided volume (ml), detrusor pressure at peak flowrate, Pdet.Qmax (cmH2O), maximum flowrate, Qmax (ml/s), post void residual (ml).

Pilot 3:
Uroflowmetry parameters measured using the Minze HomeFlow device throughout the two week trial. Parameters include voided volume (ml), maximum flow rate (ml/s), average flow rate (ml/s) and shape of flow.

Key secondary outcome(s)
Pilot 1 and 2:
-Bladder diary parameters recorded during the two week trial. Parameters include voided volume (ml), number of voids /day and number of incontinence episodes / day.
-Patients subjective response to treatment measured using the ICIQ-OAB questionnaire on day 4, 9 and 14.

Pilot 3:
-Patients subjective response to treatment measured using the ICIQ-FLUTS questionnaire on day 4, 9 and 14.

Completion date
01/10/2026

Eligibility

Key inclusion criteria
Study 1 and 2: Male and female patients with refractory OAB symptoms, diagnosed with DO on UDS
Study 3: Female patients with refractory voiding dysfunction and evidence of high-tone non-relaxing sphincter on UDS and urethral pressure profilometry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Anatomical abnormalities in the genitalia or pelvic region
2. Women who plan to become pregnant
3. Patients expecting to have diathermy treatment
4. Patients with neurological disease
5. Anticoagulants
6. Any other condition that would prevent the patient from completing the study, as judged by the principal investigator
7. Involvement in other current or recent research trials (3 months)
8. Non-English speaking and those lacking capacity

Date of first enrolment
01/11/2024

Date of final enrolment
02/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
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SE19RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR

https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	10/07/2024	26/09/2024	No	Yes
Participant information sheet	version 3.0	10/07/2024	26/09/2024	No	Yes
Participant information sheet	version 3.0	10/07/2024	26/09/2024	No	Yes