Plan Overview

A Data Management Plan created using DeiC DMP

Title: Sacral neuromodulation for neurogenic lower urinary tract, bowel and sexual dysfunction

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Project abstract:

Patients with multiple sclerosis (MS) frequently suffer from pelvic-organ dysfunctions, i.e. bladder, bowel and sexual dysfunction, aside their cerebral affection, having a serious impact on quality of life. Improving treatments will be of great medical and socio-economic interest. Treating neurogenic lower urinary tract dysfunction is challenging because of its complexity, progression of the neurological disease and comorbid disorders. Present treatment modalities are: Conservative therapy, medical treatments, bladder injection with OnabotulinumtoxinA and major surgical procedures such as bladder augmentation or bladder diversion surgery. Sacral neuromodulation (SNM) is a reversible minimal invasive procedure, accepted for patients with lower urinary tract dysfunction in terms of overactive bladder, dry and wet, non-obstructive urinary retention and feacal incontinence without neurological disease. Some studies indicate that SNM might be just as effective for the treatment of nLUTD. However, data is limited and the evidence level is low because of lack of randomized controlled trials. In 2020 the devices became MR-compatible which is crucial for neurological patients. We have set up a prospective randomized controlled trial to investigate the efficacy of SNM for patients with MS suffering from pelvic-organ dysfunction with regard to functional outcome and quality of life. We want to include 60 patients with MS. They will be randomized into two groups: Treatment arm with the implantable impulse generator (IPG) ON, and control arm with the IPG OFF. We will follow them for 4 months and evaluate the changes with questionnaires and urodynamics before and after treatment.

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Copyright information:

Sacral neuromodulation for neurogenic lower urinary tract, bowel and sexual dysfunction

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Data Collection

What data will you collect or create?

We will follow the patients as followed:
Pre-study investigations: Basic urological and neurological examination with free flow/rate, urodynamics, bloodtest, urine analysis, cystoscopy, renograhy, UL of the kidney.
Baseline 1 (BL1) = Inclusion of patients in the study.
Data: Bladder diary+Patient Perception of Intensity of Urgency scale (PPIUS), International Consultation on Incontinence Questionnaire (ICIQ) Male and Female Lower Urinary Tract Symptoms (MLUTS and FLUTS), ICIQ-Bowel (B), ICIQ-Male and Female Sexual function (MLUTSsex and FLUTSsex), Quality of Life (5Q-5D-5L)
After approx. three weeks:
Baseline 2 = Evaluation, before implantation of IPG. Same data as BL1 +registration of Adverse Events (reg. AE) according to the MDCG-202010/1, safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745 + Implantation Characteristics (IC)
Follow-up = One month after implantation. ICIQ-MLUTS and ICIQ-FLUTS + reg. AE + IC
Baseline 3 = End of study, four months after Evaluation. Same data as BL1 + Global Assessment Scale (GAS) + (reg. AE). Study converts into open label study + IC
Baseline 4 = End of open label study. Same data as BL1 + (reg. AE) + GAS + IC

How will the data be collected or created?

The investigations at baseline is part of the normal investigation programme for neurological patients with urinary symptoms. All the information will be collected and reported ind the database created in REDCap as part of OPEN. The information will be accesible in The Public Electronic Journal System.
The data from the bladder diary will be interpreted and transferred to the data system i REDCap for later analyzation.
The other questionnaires will be sent out via REDCap, OPEN, Odense Patient data Explorative Network, Odense University Hospital, to the Electronic Letter-boxes (E-boks) of the patients. They in turn will answer the questions electronically and return the answers to REDCap.
In REDCap the questionnaires with be filed under corresponding names to be able to distinguish among all the data in the time table, that has been prepared for the study.
The data will be achieved by the primary investigator and the study coordinator associated with the project.
The final data analysis will be done by a blinded statistician.

Documentation and Metadata

What documentation and metadata will accompany the data?

This study will be registered in ClinicalTrials.gov.
The protocol and the Statistical Analysis Plan will be submitted to BMJ Open for the purpose of publication.

Ethics and Legal Compliance

How will you manage any ethical issues?

Ethics approval for the conduct of this study was obtained from the Ethics Committee Southern Denmark on the 31st of May 2021 with the project ID S-20210030
All participants are treated according to current clinical standards regardless of the randomized study participation. The participants are volunteers and can at any moment withdraw their participation in the study without affecting their current or future treatment rights.
The Informed Consent form will be found online as an online supplementary file or handed out and it will be signed by all participants willing to participate the study and stored in their electronic journals in Department of Urology, Odense University Hospital. All patients are given both oral and written information about the study.
The project is approved by the Danish Data Protection Agency 21/31796 in Region South Denmark.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The above plan creator have agreed that others may use as much of the text of this plan as they would like in their own plans, and customise it as necessary. You do not need to credit the creator as the source of the language used, but using any of the plan's text does not imply that the creator endorse, or have any relationship to, your project or proposal

Storage and Backup

How will the data be stored and backed up during the research?

The project is registered at OPEN, Open Patient data Explorative Network, Odense University Hospital, Odense, Denmark with file number: OP_1411.
The project is approved by the Danish Data Protection Agency 21/31796 in Region South Denmark.

How will you manage access and security?

During data collection data is continually stored and updated in REDCap, hosted by OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark Region of Southern Denmark.
Permanent storing and storing on temporary data sets will be in OPEN.
The data are backed up by the host's IT department.
REDCap allows for detailed and differentiated user access. Only project employees with need to access data will be given permission to do so.

By keeping versioned copies of all processing scripts, we ensure that our data processing steps and arguments can be followed by interested parties.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All of the data included in the project. The data has the potential to be used for further investigation such as follow-up studies.

What is the long-term preservation plan for the dataset?

The data will be preserved for ten years. After this period the data is considered irrelevant for further investigation and will be destroyed.

Data Sharing

How will you share the data?

The data will be handle in accordance with the FAIR principles:
All data files will be stored in OPEN (Odense Patient explorative network) analyze.
REDCap will be used as database to store measurement data and patient reported outcomes and for generating randomizations.
All identifiers will be removed before publication.
All the data will be anonymized.
The data will be analyzed and interpreted and a publication plan will be prepared for presenting data for further information. The publication strategy will include DOI-number and contact information for further questions according to the findings.
Publications will be in terms of:
Articles, presentations at congresses, abstracts, thesis for PhD

Are any restrictions on data sharing required?

All data will be anonymized and you will have to ask for copyright permission to use data.

Responsibilities and Resources

Who will be responsible for data management?

Data capture: Hanne Kobberø
Metadata production: Hanne Kobberø
Data quality: Hanne Kobberø
Storage and backup: OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark
Data archiving:OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark
Data sharing: Hanne Kobberø

What resources will you require to deliver your plan?

OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark is fundamental for storage and back-up. Introduction and training with this platform is fundamental for the use.