ISRCTN68115364 https://doi.org/10.1186/ISRCTN68115364

Experiences and quality of life in children and their parents treated with nerve stimulation for urinary incontinence

Submission date
26/06/2022

Recruitment status
No longer recruiting

Registration date
27/06/2022

Overall study status
Completed

Last Edited
05/12/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Posterior tibial nerve stimulation (PTNS) is one of the treatment modalities for children with lower urinary tract dysfunction (LUTD).
Lower Urinary Tract Dysfunction, also known as dysfunctional voiding, is a condition that affects many children and is generally not a serious problem but is certainly a nuisance. Dysfunctional voiding is generally felt to be a dis-coordination between the bladder and the bladder outlet. This study is a mixed-methods analysis to gain insight into the experiences of children treated with PTNS and their parents, the effect of treatment on Quality of Life (QOL) and effect of PTNS on urinary symptoms.

Who can participate?
Children with lower urinary tract dysfunction receiving posterior tibial nerve stimulation (PTNS) treatment and their parents

What does the study involve?
A single-center retrospective chart analysis of all children between 6-12 years of age with LUTD treated with PTNS in a group setting between 2016-2021. Voiding parameters and QOL scores before and after treatment are compared. Qualitative outcomes are assessed by an explorative study involving semi-structured interviews transcribed verbatim and inductively analysed using the constant comparative method. Interviews are done between October 2021-December 2021.

What are the possible benefits and risks of participating?
There are no risks or direct potential benefits for participants. Potential burden for the individual subjects is mainly time consummation of 45 minutes.

Where is the study run from?
Radboud University Medical Center, Amalia Children's Hospital (the Netherlands)

When is the study starting and how long is it expected to run for?
September 2021 to December 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Liesbeth de Wall, liesbeth.dewall@radboudumc.nl

Contact information

Type(s)
Principal investigator

Contact name
Dr Liesbeth de Wall

ORCID ID
https://orcid.org/0000-0002-1704-6772

Contact details
Geert grooteplein zuid 10
Nijmegen
Netherlands
6500HB
+31-24-3613735
liesbeth.dewall@radboudumc.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
METC Arnhem-Nijmegen 2021-13133

Study information

Scientific Title
Experiences with posterior tibial nerve stimulation in children and their parents, Quality of life and effect on lower urinary tract dysfunction. A mixed methods analysis.

Acronym
PTNS and QOL

Study objectives

How do parents and children experience PTNS? How does PTNS treatment effect Quality of life in children with urinary symptoms and their parents? How does QOL change during treatment? What is the outcome of PTNS on urinary symptoms? We hypothesize an improvement of both OQL and urinary symptoms after treatment with PTNS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2021, Medical Ethics Committee METC Arnhem-Nijmegen (Nijmegen, the Netherlands; METCoost-en-CMO@radboudumc.nl; +31-243613154), ref: 2021-13133

Study design
Mixed methods study (quantitative and qualitative analysis). Retrospective chart analysis (quantitative) and explorative qualitative study with semi-structured interviews

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Quality of life and experiences with neuromodulation in children with lower urinary tract dysfunction

Interventions
Quantitative outcomes were assessed trough a single-center retrospective chart analysis of all children treated with PTNS in a group setting between 2016-2021. Voiding parameters and QOL scores before and after treatment were compared. Qualitative outcomes were assessed by an explorative study involving semi-structured interviews transcribed verbatim and inductively analysed using the constant comparative method.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Experiences of children and their parents assessed by an explorative study involving semi-structured interviews transcribed verbatim and inductively analysed using the constant comparative method.

Key secondary outcome(s))
Measured using patient records at a single time point (retrospective analysis):
1. Change in QOL before and after treatment
2. Effect of PTNS on urinary symptoms
3. Change in maximum and average voided volume throughout treatment

Completion date
28/12/2021

Eligibility

Key inclusion criteria
Children with lower urinary tract dysfunction receiving posterior tibial nerve stimulation (PTNS) treatment and their parents

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
101

Key exclusion criteria
1. Children not receiving PTNS
2. Children and or parents not willing to participate in the interviews

Date of first enrolment
01/10/2021

Date of final enrolment
15/12/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Medical Center, Amalia Children's Hospital
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6500HB

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request: Dr.LL de Wall, liesbeth.dewall@radboudumc.nl. This include anonymised data of participants, SPSS data and transcribed data in Atlas.ti. Data are available after publication and after a data transfer agreement and for academic purposes only.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/07/2022	05/12/2022	Yes	No
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Protocol file		01/08/2021	27/06/2022	No	No