

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

<b>Submission date</b> 26/06/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/12/2022	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> 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 consumption 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](mailto:liesbeth.dewall@radboudumc.nl)

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Liesbeth de Wall

### ORCID ID

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **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 measure**

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.

## **Secondary outcome measures**

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

## **Overall study start date**

02/09/2021

## **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

## **Age group**

Child

## **Sex**

Both

## **Target number of participants**

101

## **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

**Sponsor details**  
Amalia Children's Hospital  
Geert Grooteplein zuid 10  
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6500HB  
+31-24-3613735  
Anke.oerlemans@radboudumc.nl

**Sponsor type**  
Hospital/treatment centre

**Website**  
<https://www.radboudumc.nl/EN/Pages/default.aspx>

**ROR**  
<https://ror.org/05wg1m734>

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## Results and Publications

Publication and dissemination plan

Planned publication in journal: international journal of Environmental Research and Health

### Intention to publish date

01/12/2022

### 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?
<a href="#">Protocol file</a>	version 1	01/08/2021	27/06/2022	No	No
<a href="#">Results article</a>		25/07/2022	05/12/2022	Yes	No