

# Long-term outcome of childhood urinary symptoms

<b>Submission date</b> 04/11/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/11/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/12/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Lower urinary tract dysfunction (LUTD) in childhood might affect both lower urinary tract function and psychosocial wellbeing later on in life. The long-term outcome and prognosis are largely unknown.

The aim of this study is to evaluate the long-term functional and psychosocial outcome of adolescents and young adults treated for childhood LUTD and compare these outcomes to healthy age-related controls and treatment outcome in the past.

### Who can participate?

Former patients treated for childhood LUTD, currently aged 16-26 years, and a healthy control group

### What does the study involve?

Both former patients and controls complete a four-part paper survey composed of validated questionnaires measuring LUTD, general- and disease-specific quality of life and mental health.

### What are the possible benefits and risks of participating?

There are no benefits or risks involved in participation.

### Where is the study run from?

January 2018 to June 2020

### When is the study starting and how long is it expected to run for?

Radboud University Medical Center, Amalia's Children's Hospital (Netherlands)

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr LL de Wall  
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# Contact information

## Type(s)

Public

## Contact name

Ms 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

PANAMA 108187

# Study information

## Scientific Title

Long-term functional and psychosocial outcome at adolescence and young adulthood of patients treated for lower urinary tract dysfunction in childhood

## Acronym

LUCOS

## Study objectives

A hypothesized 25% more lower urinary tract symptoms (LUTS) are expected in former patients versus healthy age-related controls.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 20/03/2018, local ethics committee (CMO Arnhem-Nijmegen, p/a Radboudumc, huispost 628, Postbus 9101, 6500 HB Nijmegen, The Netherlands; +31 (0)24 361 3154; tc@ccmo.nl), ref: NL 64311.091.17

## **Study design**

Single-center observational cohort study

## **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 written in Dutch

## **Health condition(s) or problem(s) studied**

Long term psychosocial and functional outcome of former patients treated for childhood lower urinary tract dysfunction

## **Interventions**

After informed consent, a four-part paper survey is sent including questions about demographics, psychiatric co-morbidity, LUTS (Lower Urinary Tract Symptoms), general and disease-specific quality of life (DSQOL) and mental health. A healthy age-related control group receive the same survey. Validated existing questionnaires are used: the overactive bladder questionnaire to assess LUTS and DSQOL, the pediatric Quality of life Inventory (PedsQol) or Short Form-36 (SF-36) to determine quality of life and the Hospital and Depression Scale (HADS) to assess mental health.

The mean follow-up time for former patients is 8.8 +/- 4.4 years after treatment in childhood. The OAB-q score for controls is the score at the time of completing the survey

## **Intervention Type**

Other

## **Primary outcome measure**

Overall number of lower urinary tract symptoms measured using the validated Overactive Bladder Questionnaire (OAB-q) score at a single timepoint

## **Secondary outcome measures**

Measured at a single timepoint:

1. Type of lower urinary tract symptoms measured using the validated Overactive Bladder Questionnaire (OAB-q)
2. General quality of life measured using Pediatric Quality of life Inventory (PedsQol) for

subjects <18 years of age and Short Form-36 Health Survey (SF-36) for subjects ≥18 years of age

3. Disease-specific quality of life measured using the OAB-q
4. Mental health outcomes measured using the validated Hospital and Depression Scale (HADS)
5. Prognostic factors for lower urinary tract symptoms later in life related to treatment outcome in the past measured using a multivariable backward regression model at time of data analysis

**Overall study start date**

01/01/2018

**Completion date**

01/06/2020

## Eligibility

**Key inclusion criteria**

1. Former patients treated for childhood lower urinary tract dysfunction (LUTD) in childhood in Radboud University Medical Center, currently between 16-26 years of age. LUTD includes any type of lower urinary tract symptom without an anatomical or neurological etiology
2. The control group is recruited by word of mouth and advertisement at the university faculty and high schools nearby

**Participant type(s)**

Mixed

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120

**Total final enrolment**

120

**Key exclusion criteria**

Anatomical or neurological conditions resulting in lower urinary tract symptoms

**Date of first enrolment**

01/04/2018

**Date of final enrolment**

01/06/2020

## Locations

**Countries of recruitment**

Netherlands

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

## Sponsor information

**Organisation**  
Radboud University Nijmegen Medical Centre

**Sponsor details**  
Amalia Children's Hospital  
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6500 HB  
+31 (0)24 3613735  
liesbeth.dewall@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**  
Hospital/treatment centre

**Funder Name**  
Radboud Universitair Medisch Centrum

**Alternative Name(s)**  
Radboudumc, Radboud University Medical Center, Radboud University Nijmegen Medical Center, RUNMC

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Netherlands

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/06/2021

**Individual participant data (IPD) sharing plan**

The researchers use CASTOR for data management, furthermore, studies are registered in PANAMA, this study is registered under number 108187. For analyses, data are loaded in SPSS as CASTOR is not able to do that. The data stored are the filled-in 4-part paper surveys and informed consents of all subjects. All data are anonymised and only the principal investigator has access to the actual identification of subjects.

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			05/11/2020	No	No
<a href="#">Results article</a>		03/09/2021	07/12/2021	Yes	No