# Long-term outcome of childhood urinary symptoms

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
04/11/2020	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
04/11/2020	Completed	[X] Results
<b>Last Edited</b> 07/12/2021	Condition category Urological and Genital Diseases	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

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### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

**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

#### Study type(s)

Quality of life

#### 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(s)

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

#### Key secondary outcome(s))

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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

#### **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**

#### 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** 

Results article		03/09/2021	07/12/2021 Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes
<u>Protocol file</u>			05/11/2020 No	No