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Long-term outcome of childhood urinary symptoms

Submission date
04/11/2020

Recruitment status
No longer recruiting

Registration date
04/11/2020

Overall study status
Completed

Last Edited
07/12/2021

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
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?
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Contact information

Type(s)
Public

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Additional identifiers

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

Primary study design
Observational

Study design

Single-center observational cohort study

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
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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	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/09/2021	07/12/2021	Yes	No
Protocol file			05/11/2020	No	No