

# Low dose chemoprophylaxis (LDCP) and reduction of pyelonephritic episodes and significant bacteriuria in children with meningomyelocele and clean intermittent catheterisation (CIC)

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/01/2017	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
NTR164

# Study information

## Scientific Title

Low dose chemoprophylaxis (LDCP) and reduction of pyelonephritic episodes and significant bacteriuria in children with meningomyelocele and clean intermittent catheterisation (CIC)

## Acronym

SPIN UTI study

## Study objectives

In meningomyelocele (MMC)-children treated with clean intermittent catheterisation (CIC), the incidences of significant bacteriuria and pyelonephritic episodes are only slightly smaller in the group of subjects treated with low dose chemoprophylaxis (LDCP) compared to the group without LDCP.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

## Study design

Multicentre randomised active-controlled parallel-group trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Meningomyelocele (MMC)

## Interventions

The entire group with MMC and CIC is allocated randomly continuing LDCP or stopping LDCP.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

1. Number of urinary tract infections
2. Number of pyelonephritic episodes

## Key secondary outcome(s)

Changes in antibiotic resistance patterns in the cultured uropathogens

**Completion date**

01/05/2008

## Eligibility

**Key inclusion criteria**

1. Neuropathic bladder-sphincter dysfunction
2. CIC and use of LDCP for at least 6 months
3. Good possibilities for communication
4. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Key exclusion criteria**

1. Urinary tract infection (UTI) or - pyelonephritis at inclusion
2. Fever of unknown origin (e causa ignota [ECI])
3. Other neurologic diseases
4. Other diseases like IDDM that can cause UTI

**Date of first enrolment**

21/02/2005

**Date of final enrolment**

01/05/2008

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Centre Utrecht

Utrecht

Netherlands

3508 AB

# Sponsor information

## Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

## ROR

<https://ror.org/04pp8hn57>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Wilhelmina Research Fund (Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2011		Yes	No
<a href="#">Results article</a>	results	12/01/2017		Yes	No