

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

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/01/2017	Condition category Other	☐ 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

Primary study design

Interventional

Study design

Multicentre randomised active-controlled parallel-group trial

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?
Results article	results	01/12/2011		Yes	No
Results article	results	12/01/2017		Yes	No