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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
16/01/2017

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
Changes in antibiotic resistance patterns in the cultured uropathogens

Overall study start date
21/02/2005

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

Age group
Child

Sex
Both

Target number of participants
170

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)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Research organisation

Funder Name
Wilhelmina Research Fund (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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