Antibiotic prophylaxis in prevention of urinary tract infections caused by removal of a bladder catheter in children

Submission date	Recruitment status	[X] Prospectively registered
11/04/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/04/2007	Completed	Results
Last Edited	Condition category	Individual participant data
22/09/2021	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number NL899 (NTR923)

Study information

Scientific Title

Antibiotic prophylaxis in prevention of urinary tract infections caused by removal of a bladder catheter in children

Acronym

AUB study

Study objectives

A short course of amoxicillin/clavulanic acid will not reduce the number of urinary tract infections in children that have been catheterised during a short period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised, double blinded, placebo controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Urinary tract infections, bladder catheterisation in children

Interventions

Amoxicillin/clavulanic acid prophylaxis versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Amoxicillin/clavulanic acid

Primary outcome(s)

Urinary tract infection (positive urine culture)

Key secondary outcome(s))

- 1. Bacteriuria
- 2. Side effects of antibiotics

Completion date

01/06/2009

Eligibility

Key inclusion criteria

- 1. Children between zero and 18 years
- 2. Short term (greater than two hours, less than seven days) bladder catheterisation
- 3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 years

Sex

Not Specified

Key exclusion criteria

- 1. Use of antibiotics
- 2. Renal function disorders
- 3. Allergy to antibiotics

Date of first enrolment

01/06/2007

Date of final enrolment

01/06/2009

Locations

Countries of recruitment

Netherlands

Study participating centre Onze Lieve Vrouwe Gasthuis

Amsterdam Netherlands 1090 HM

Sponsor information

Organisation

Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

ROR

https://ror.org/01d02sf11

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration