ISRCTN65525844 https://doi.org/10.1186/ISRCTN65525844

# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
Urinary tract infection (positive urine culture)

### Secondary outcome measures
1. Bacteriuria
2. Side effects of antibiotics

### Overall study start date
01/06/2007

### 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

### Age group
Child

### Upper age limit
18 Years

### Sex
Not Specified

### Target number of participants
94

### 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
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# Sponsor information

**Organisation**
Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

**Sponsor details**
Department of Pediatrics
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.olvg.nl/

**ROR**
https://ror.org/01d02sf11

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Onze Lieve Vrouwe Gasthuis (OLVG) (The 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