

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

| | | |
|--|--|--|
| Submission date 11/04/2007 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 11/04/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 22/09/2021 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr A M Bouwman

Contact details

Onze Lieve Vrouwe Gasthuis
Department of Pediatrics
P.O. Box 95500
Amsterdam
Netherlands
1090 HM

-

a.m.bouwman@olvg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Netherlands

1090 HM

Sponsor information

Organisation

Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

Sponsor details

Department of Pediatrics

P.O. Box 95500

Amsterdam

Netherlands

1090 HM

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