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

Published: 07-08-2007
Last updated: 08-05-2024

The goal of this study is to determine whether a short course of amoxicillin/clavulanic acid reduces the number of urinary tract infections in children that have been catheterized during a short period.

Ethical review	Approved WMO
Status	Pending
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON30723

Source
ToetsingOnline

Brief title
AUB-study

Condition

- Urinary tract signs and symptoms

Synonym
bladder infection, cystitis

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: gereserveerd bedrag hoofdonderzoeker/ unit kindergeneeskunde

Intervention

Keyword: antibiotics, bladder catheter, children, urinary tract infection

Outcome measures

Primary outcome

urinary tract infection (positive urine culture)

Secondary outcome

- bacteriura

- side-effects of antibiotics

Study description

Background summary

Urinary tract infections are frequently seen in childhood, presenting by a range of symptoms. It is a well know believe that urinary tract infections can be caused by the removal of a bladder catheter. There are several hypotheses about this mechanism: during removal of a catheter micro-lesions in the bladder and urethra epithelium can be caused, which may act as a porte d'entree for micro-organisms, or possibly, there's shortly a less efficient bladder function.
Often antibiotics are prescribed as prophylaxis during the removal of a bladder catheter in children, although there is no scientific evidence.

Study objective

The goal of this study is to determine whether a short course of amoxicillin/clavulanic acid reduces the number of urinary tract infections in children that have been catheterized during a short period.

Study design

Randomized, double-blind placebo-controlled multicenter clinical trial.
The study will be started in the Onze Lieve Vrouwe Gasthuis and VU Medical Center, followed by the Sint Lucas Andreas Hospital, Zaans Medical Center and Kennemer Gasthuis. During a maximum of two years children will be recruited between 0 and 18 years, that need a bladder catheter more than two hours, less than 7 days. Informed consent will be needed. Exclusion criteria: pre-existent

use of antibiotics, renal function failure, allergy to amoxicillin or symptomatic bacteriuria.
Demographics will be listed and parents will be asked to fill in a questionnaire. There will be block randomisation by means of envelopes.
Two hours before the removal of the catheter the short course amoxicillin/clavulanic suspension, or placebo, will be started; the course will be curing 48 hour, 50/12,5 mg/kg in 3 times, with a maximum of 3dd500/125mg.
Parents and their children will be asked to fill in other questionnaires after 1 and 3 weeks, and to collect urine, which will be analyzed and be cultured.
For statistal analysis a Fisher's exact test will be used. The study is designed to detect a possible difference of 20% in the occurence of urinary tract infections between the antibiotica and placebo-group, with a 95% confidence interval and a power of 80%, assuming an a priori change of 5% of the occurence of an urinary tract infeciton in children, caused by the removal of a bladder catheter. Following calculation with the Fisher's exact test, 47 patients a group, meaning a total of 94 patients have to be included.

Intervention

amoxicillin/clavulanic acid (50/62,5mg/kg, max. 3 times a day 500/125mg) versus placebo

Study burden and risks

The burden will be having to take the antibiotics; usually this is not a problem, because of the sweet taste of amocillin/clavulanic acid. Possibly there is the risk of developing diarrea as a side-effect.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Postbus 95500
1090 HM Amsterdam
Nederland
Scientific
Onze Lieve Vrouwe Gasthuis

Postbus 95500
1090 HM Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- bladder catheter (>2 hours, < 7 days)
- informed consent

Exclusion criteria

- use of antibiotics
- renal function disorder
- amoxicillin/clavulanic acid allergy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	94
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Augmentin
Generic name:	amoxicillin/clavulanic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-006218-14-NL

Register	ID
Other	ISRTCN nummer volgt
CCMO	NL15306.067.07