Exploring prophylactic co-trimoxazole regimens at the removal of temporary catheters to prevent urinary tract infections: a randomised placebo controlled pilot study

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To determine a suitable co-trimoxazole regimen for testing in a future larger clinical trial to determine the efficacy of antibiotic prophylaxis in patients with a temporary urinary tract catheter.

Ethical review	Not approved
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON35979

Source
ToetsingOnline

Brief title
Exploring co-trimoxazole regimens

Condition

- Bacterial infectious disorders

Synonym
cystitis, urinarary tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: Stichting apotheek haarlemse ziekenhuizen (SAHZ)

Intervention

Keyword: antibiotic prophylaxis, co-trimoxazole, urinary tract catheter

Outcome measures

Primary outcome

the course of the percentage of subjects with bacteriuria in seven days after

intervention.

Secondary outcome

the percentage of subjects with an urinary tract infection at any moment in

seven days after intervention

Study description

Background summary

Short-term catherisation is widely applied in a hospital setting. All patients with a urinary tract catheter develop bacteriuria in time. The catheter creates a port of entry for micro-organisms and the mechanical wash-out of bacteria by urine stream is interrupted. The prevalence of this bacteriuria is 3 tot 7 % per catherisation day. An asymptomatic bacteriuria mostly resolves spontaneously within 14 days after catheter removal. Asymptomatic bacteriuria after short term catheter use becomes symptomatic in 15% of the patients within 48 hours.
A questionnaire sent to healthcare professionals in the United Kingdom revealed that 60% advocated the use of prophylactic antibiotics at the withdrawal of catheters in all or selected groups of patients. In contrast, a restrictive policy for the prescription of antibiotics is followed in the Netherlands compared with other countries in Europe. This low consumption of antibiotics correlates with relatively low resistance to antibiotics. The restrictive antibiotic policy and a lack of evidence explains, that routine antibiotic prophylaxis at the removal of urinary tract catheters is not recommended in the

Dutch guidelines. In contrast urinary tract infections increase costs and morbidity of patients substantially. The usefulness of antibiotic prophylaxis was therefore investigated in some studies.
Results of a small randomised double-blind placebo controlled pilot study with ciprofloxacin at 500mg, twice a day and four doses did not support the benefit of prophylactic ciprofloxacin to reduce the rate of urinary tract infections.
In a second study, ciprofloxacin at 500mg, twice a day, and six doses was compared with no antibiotic treatment after laparoscopic radical prostatectomy. The results of this study demonstrated significant benefit of ciprofloxacin.
Results of a study including female patients only did not indicate a significant decrease of bacteriuria after treatment with a single dose compared with a ten days treatment of co-trimoxazole (trimethoprim-sulfamethoxazole) at 1600/320mg once and 800/160mg twice a day. In an other randomized prospective study a significant benefit of trimethoprim-sulfamethoxazole at 800/160mg twice a day and three doses was demonstrated in elective abdominal surgery patients.
The results of the studies do not unequivocally advocate antibiotic prophylaxis. In addition, the experimental set-up differed considerably among the studies hampering the set-up of a large clinical trial to demonstrate the efficacy of antibiotic prophylaxis. Here, we explore antibiotic prophylaxis further in a pilot study. We choose trimethoprim-sulfamethoxazole as investigational medical product as it may be used in man and woman. In addition it is effective against a broad range of micro-organisms. Our goal is to determine a dosing regimen of co-trimoxazole suitable for testing in a future larger clinical trial to determine the efficacy of antibiotic prophylaxis in patients with a temporary urinary tract catheter.

Study objective

To determine a suitable co-trimoxazole regimen for testing in a future larger clinical trial to determine the efficacy of antibiotic prophylaxis in patients with a temporary urinary tract catheter.

Study design

Doubleblind placebo-controlled three arms pilot intervention study

Intervention

Trimethoprim-sulfamethoxazole or placebo.

Study burden and risks

All patients in this trial will have to collect some urine samples.
In addition the occurrence of an urinary tract infection in time will be examined by using a short questionnaire. The estimated time of filling out the questionnaire is 5 minutes.

Subjects in the trimethoprim-sulfamethoxazole intervention groups have a risk of side effects of the IMP depending on the intervention group they are included, but there is probably a lower risk of urinary tract infections and resulting complications of these.
Patients in the placebo group have no risk of side effects due to co-trimoxazole but have probably a higher risk of urinary tract infections and complications.
Trimethoprim-sulfamethoxazole is an antibiotic which is registered in 1972. Allergic reactions like exanthema are the most frequently reported side effects. In case of allergy the medication will be discontinued. The IMP has common side effect like hyperkalemia, hyponatremia nausea, diarrhoea and vomiting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Temporary urinary catheter for minimal 2 days
Bacteriuria defined as more then 10^ 5 cfu/ ml
Age of 18 years or older
Signed informed consent

Exclusion criteria

Antibiotic treatment of less than 1 week prior to the removal of the urinary catheter
Urogenital surgery
Pregnancy or breast feeding
Known allergy to sulfamethoxazol or trimetoprim
Renal insufficiency defined as MDRD less then 30ml/ minute
Symptomatic urinary tract infection
Co-medication interacting with sulfamethoxazole or trimetoprim upon discretion of the investigators

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	42
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	co-trimoxazole (trimethoprim-sulfamethoxazole)
Generic name:	co-trimoxazole (trimethoprim-sulfamethoxazole)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-07-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Not approved Date:	25-07-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2011-002815-27-NL
CCMO	NL35944.029.11