Shorter treatment of catheter-related urrinary tract infections

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26262

Source
NTR

Brief title
SHORTCUT

Health condition

catheter, UTI, urinary tract infection, antibiotic stewardship, catheter-related, urineweginfectie, catheter-gerelateerd

Sponsors and support

Primary sponsor: Department of Infectious Diseases, Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The primary study endpoint is the recurrence of a symptomatic UTI during 90 days after randomization.

Secondary outcome

- recurrence of a symptomatic UTI during 180 days after randomization.

- time to recurrence of symptomatic UTI

- clinical and microbiological cure at end-of-treatment

- results of urine cultures at day 30 and day 90 after randomization

- resistance pattern of cultured microorganisms after end-of-treatment

- total antibiotic consumption, overall and for UTI during 90 days after randomization

- acute hospitalizations for UTI during 90 days after randomization

- C. difficile associated diarrhea during 90 days after randomization

Study description

Background summary

Rationale:

UTI is the most common infection experienced by residents of nursing homes, and the most frequently reported indication for antibiotic prescribing. The optimal treatment duration for symptomatic CA-UTI is unknown. A few small studies suggest that short courses might be adequate in CA-UTI, but at present the evidence is not conclusive, as the power and design of these studies are limited. It is desirable to limit the duration of treatment of CA-UTI to reduce the selection pressure for drug-resistant flora, especially in patients on long-term catheterization.

Objective:

The primary objective is to establish the non-inferiority of treating a symptomatic urinary tract infection in patients with a long-term indwelling catheter for 5 days, as compared to the standard duration of 10 days of therapy. Secondary objectives are to establish differences between the two treatment durations in resistance pattern of cultured microorganisms, total antibiotic consumption, overall and for UTI, incidence of acute hospitalizations for infection and incidence of C. difficile associated diarrhea.

Study design:

A non-blinded, randomized controlled trial.

Study population:

Patients with a longterm indwelling catheter who develop signs/symptoms of a UTI.

Intervention:

The intervention group will receive 5 days of antibiotic therapy, as compared to 10 days in the control group.

Main study parameters/endpoints:

The primary study endpoint is the recurrence of a symptomatic UTI during 90 days after randomization. Secondary study endpoints are: recurrence of a symptomatic UTI, time to recurrence of symptomatic UTI, clinical and microbiological cure at end-of-treatment, results of urine cultures at day 30 and day 90 after randomization, resistance pattern of cultured microorganisms after end-of-treatment, total antibiotic consumption, overall and for UTI during 90 days after randomization, acute hospitalizations for infection and C. difficile associated diarrhea during 90 days after randomization.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
After treatment for the UTI, participants will return for 4 short visits to the hospital/rehabilitation centre to hand in a urine sample and a short interview regarding symptoms/complaints of UTI. If patients develop new complaints, they will be asked to contact research physician for evaluation. There is a small risk associated with shorter treatment of CA-UTI, as the non-inferiority yet had to be investigated, although previous studies do not show increased risk associated with shorter treatment. This study will not benefit patients and investigators directly, but will benefit the general community.

Study objective

Treating a symptomatic urinary tract infection in patients with a long-term indwelling catheter for 5 days is non-inferior compared to the standard duration of 10 days of antibiotic therapy with regard to clinical cure rate.

Study design

The primary endpoint is 90 days after randomisation.

Secondary endopoints are up to 180 days after randomisation.

Intervention

Patients will be treated with antibiotics according to SWAB/Verenso guideline. In the intervention arm, patients will receive 5 days of therapy. In control arm will receive 10 days of antibiotic treatment according to current guideline.

Patients with a indwelling catheter may carry the usual flora, such as Enterobacteriaceae and enterococci, but also Pseudomonas spp., Serratia spp., Providencia spp. and Acinetobacter spp.. Therefore a double-blind trial is not feasible, as the treatment should be tailored to the cultured microorganism.

Contacts

Public
Academic Medical Center Amsterdam, F4-106

J.E. Oryszczyn
P.O. box 22660

Amsterdam 1100 DD
The Netherlands
020-5666807
Scientific
Academic Medical Center Amsterdam, F4-106

J.E. Oryszczyn
P.O. box 22660

Amsterdam 1100 DD
The Netherlands
020-5666807

Eligibility criteria

Inclusion criteria

1. Indwelling (transurethral or supra-pubic) urinary catheter with the intention for long term continuous catheterization, and at least for the next 28 days

2. Signs/symptoms of a systemic UTI, following the modified Loeb criteria [23,24]: a. patient feels sick; b. at least one of the following signs: Fever > 37.9 ºC, Rigors, New onset delirium, New/worsened costovertebral angle tenderness or other local signs of UTI

3. Positive dipstick leucocyte esterase test, or sediment > 10 leucocytes/mm3

Exclusion criteria

1. Evidence of acute prostatitis or epididymitis

2. Negative urine culture after 3 days, sampled before start of antibiotics.

3. Insufficient understanding of Dutch or English language, or otherwise unable (cognitively impaired or incapacitated) to understand or cooperate in study, or to give informed consent.

4. Patients younger than 18 years of age.

5. Current pregnancy

6. Patients with kidney transplant.

7. Patients with suspected concomitant infection requiring antibiotic treatment

8. Patients with planned removal of catheter or switch to intermittent catheterization within 28 days (4 weeks) after inclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-09-2017
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-07-2017
Application type:	First submission

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
NTR-new	NL6355
NTR-old	NTR6539
Other	ZonMW : 50-54100-98-108

Study results

Summary results
None.