Shorter treatment of catheter-related urinary tract infections

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON46655

Source
ToetsingOnline

Brief title
SHORTCUT

Condition

- Bacterial infectious disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym
bladder infection, urinary tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: antibiotic stewardship, catheter, CA-UTI, urinary tract infection

Outcome measures

Primary outcome

The primary study endpoint is the recurrence of a symptomatic UTI during 90 days after end-of-treatment. Relapse and reinfction will be distinguished according to current guidelines with a modification for patients with a urinary catheter. Recurrent bacteriuria is defined as eradication of the initial infecting bacterial species followed by a new episode of bacteriuria after end-of-treatment; relapse in case of presence of the initial infecting micro-organism, and reinfection in case of different micro-organism.

Secondary outcome

Secondary study endpoints are: recurrence of a symptomatic UTI during 180 days after end-of-treatment, 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 end-of-treatment, resistance pattern of cultured microorganisms after end-of-treatment, total antibiotic consumption (overall and for UTI) during 90 days after end-of-treatment, acute hospitalizations for urinary tract infection and C. difficile associated diarrhea during 90 days after end-of-treatment.

Study description

Background summary

Urinary tract infection (UTI) is a very common infection in hospitalized patients and residents of nursing homes and rehabilitation clinics. It is the most frequently reported indication for antibiotic prescribing, accounting for 32% to 66% of the prescriptions in nursing homes. Especially patients with a urinary catheter are at an increased risk. 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.

Study 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 urinary tract infection and incidence of C. difficile associated diarrhea, and to gain insight into the accuracy of the modified Loeb criteria to diagnose catheter-related urinary tract infections.

Study design

A non-blinded, randomized controlled trial with blinded endpoint assesment.

Intervention

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

Study burden and risks

After treatment for the UTI, participants will return for 5 short visits to the hospital/rehabilitation centre to hand in a urine sample and a short interview regarding symptoms/complaints of UTI. At the end of follow up patients will have one short interview by telephone. If a patient develops new complaints, he/she will be asked to contact the research physician for evaluation. There is a small risk associated with shorter treatment of CA-UTI, as the non-inferiority is to be investigated, although previous studies do not show an increased risk associated with shorter treatment. This study will not benefit patients and investigators directly, but will benefit the general community.

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

At presentation with current episode of catheter related urinary tract infection:
1. Indwelling (transurethral or supra-pubic) urinary catheter with the intention for long-term continuous catheterization, 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; In patients with spinal cord injury: increase of spasticity.
3. Positive dipstick leucocyte esterase test, or sediment > 10 leucocytes/mm3. If a dipstick or sediment was not performed, a positive urine is needed.

Exclusion criteria

1. Evidence of acute prostatitis or epididymitis
2. 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.
3. Patients younger than 18 years of age.
4. Current pregnancy
5. Patients with kidney transplant.
6. Patients with suspected concomitant infection requiring antibiotic treatment
7. Patients with growth of S. aureus or pseudomonas spp in blood culture.
8. Patients that cannot be treated with (combinations of) the following antibiotics: amoxicillin, amoxicillin/clavulanic acid, cefuroxime, cefotaxime, ceftriaxone, ceftazidime, meropenem, gentamicin, tobramycin, ciprofloxacin, cotrimoxazole, vancomycin.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2018
Enrollment:	300
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Amoxicillin
Generic name:	amoxicillin
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Augmentin
Generic name:	amoxicillin/clavulanic Acid
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cefotaxime
Generic name:	cefotaxim
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ceftazidime
Generic name:	ceftazidim
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rocephin
Generic name:	ceftriaxone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-02-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	11-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2019
Application type:	Amendment
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	EUCTR2017-003975-80-NL
CCMO	NL63574.018.17
Other	NTR6539 (Nederlands Trial Register)