The effect of direct urinary catheter replacement among adults with UTI, systemic manifestations and indwelling catheter in comparison with replacement after two days of antibiotics.

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The purpose of this pilot study is to determine the optimal timing to replace a catheter in patients with an indwelling catheter and systematic symptoms of an UTI.

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

Summary

ID

NL-OMON46399

Source
ToetsingOnline

Brief title
Urinary catheter replacement among adults with UTI

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
Cystitis, Urinary tract infection, UTI

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Subsidie van het wetenschappelijk bureau van het Deventer ziekenhuis

Intervention

Keyword: indwelling catheter, replacement, UTI

Outcome measures

Primary outcome

The primary endpoint of this study is the number of days of hospitalization.

Secondary outcome

The secondary endpoints targets the clinical effect and the safety of the

intervention.

The endpoints measuring the clinical effectiveness are *days of fever*

The endpoints measuring the safety of the intervention are patient reported

side effects, registered complications, ICU admissions, death rate, and

recurrence of UTI in 30 days after the intervention.

Study description

Background summary

Patients with an indwelling catheter are more likely to develop an urinary tract infection (UTI) than patients without an indwelling catheter. Because there is a great difference in the bacteria that cause UTI in patients with or without catheter, treatment protocol differs between these patients. While evidence exists for the antibiotic treatment in UTI patients with a catheter, there is no consensus about how to deal with the catheter itself. One study has been done to evaluate the effect of replacing the indwelling catheter in patients with symptomatic UTI. This study showed that replacing the catheter is favorable to keeping the catheter in situ. The best moment to replace the catheter remains unclear. At the Deventer Hospital, it is common practice to

replace the indwelling catheter after two days of antibiotics.
The effect of different timing in the replacement of the indwelling catheter will be examined in this study to optimize the treatment of patients with an indwelling catheter with symptomatic UTI. Besides the clinical effect we will evaluate the safety and the microbiological effect of the intervention.

Study objective

The purpose of this pilot study is to determine the optimal timing to replace a catheter in patients with an indwelling catheter and systematic symptoms of an UTI.

Study design

Prospective, randomized pilot study

Intervention

Group 1 (intervention group): After inclusion the catheter will be replaced immediately. Thereafter urine will be drawn from the new catheter for a second urine culture and antibiotics will be started.
Group 2 (Standard treatment): The catheter will be replaced after two days of antibiotic treatment.

Study burden and risks

The risk of taking part in this study is very small. We expect side effects and complications of antibiotics and replacement of the catheter in the intervention group are the same in comparison with the standard treatment. It is a small increased risk of developing a bacteremia because the catheter is removed from an infected environment whit the risk of creating lesions in the urinary tract. Theoretically there is a small increased risk of recurrence of UTI, as some pathogens can develop a biofilm on the new catheter. This limits the concentration of antibiotics that reach the pathogens.
The extent of the burden of taking part in this study is small, because the intervention does not include extra invasive procedures and does not require extra time of patients.

Contacts

Public
Deventer Ziekenhuis

A. Deusinglaan 1

Deventer 7416 SE
NL
Scientific
Deventer Ziekenhuis

A. Deusinglaan 1
Deventer 7416 SE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Presentation emergency department of the Deventer hospital
- Indwelling catheter >=10 days and indication for replacement of the catheter
- Fever >38,5C
- No other infection found that can be accountable for the fever
- Admission to a ward of DZ

Exclusion criteria

- Antibiotics <24 hours before presentation
- <18 years
- Patient to unstable to wait for the catheter replacement before the start of antibiotics.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-08-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
CCMO	NL64561.075.18