REPLACE: The impact of catheter replacement in patients with catheter-associated urinary tract infection

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The REPLACE study aims to determine whether not changing the catheter (catheter retained) for catheter-associated urinary tract infections (CAUTI)affects the recurrence-risk of CAUTI.

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

Summary

ID

NL-OMON57440

Source
ToetsingOnline

Brief title
REPLACE study

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms
- Renal and urinary tract therapeutic procedures

Synonym
catheter associated urinary tract infection (CAUTI).

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Catheter-associated urinary tract infection (CAUTI), Indwelling catheter, Recurrent infection, Urinary tract infection (UTI)

Outcome measures

Primary outcome

Primary outcome: Recurrent CAUTI within 90 days post-antibiotic treatment.

Secondary outcome

Secondary outcomes include 30-day mortality, health-related quality of life

(PROMIS, EQ-5D-5L), time to resolution of CAUTI symptoms, complications of

catheter replacement (e.g., discomfort, bleeding, sepsis), length of hospital

stay, healthcare costs, and productivity.

Study description

Background summary

With this project we aim to address knowledge question no.3 of the Urology knowledge agenda: "Is it beneficial to change bladder and kidney catheters during urinary tract infections?" There is debate regarding the usefulness of changing an indwelling catheter during antibiotic treatment of a catheterassociated urinary tract infection (CAUTI). The current guideline recommends catheter replacement, but is based on limited evidence. Our hypothesis is that there is no added value for patients to change the catheter during an antibiotic treatment for CAUTI. If refraining from catheter replacement is noninferior, this would result in a reduction of invasive procedures and reduction of healthcare associated costs. Patients with CAUTI and an indication for antibiotic treatment will be randomized to catheter replacement or no catheter replacement. The study will be conducted in academic and non-academic hospitals distributed across the country.

Study objective

The REPLACE study aims to determine whether not changing the catheter (catheter retained) for catheter-associated urinary tract infections (CAUTI)

affects the recurrence-risk of CAUTI.

Study design

This is a multicenter randomized controlled trial, utilizing a 1:1 allocation.
In total 300 participants.

Intervention

In the intervention group, the catheter is not replaced during CAUTI treatment. Choice of antibiotic agent follows standard care guidelines, with adjustments based on culture results. In this group, catheter replacement occurs according to the patient's regular schedule.

The control group undergoes catheter replacement within 3 days of starting antibiotic therapy. Choice of antibiotic agent follows standard care guidelines, with adjustments based on culture results.

Study burden and risks

Even though guidelines state that catheters should be replaced in patients with CAUTI, there is significant practice variation in the Netherlands due to the limited evidence. In practice, this means that both changing the catheter as well as retainment is standard care.

Both treat-ments have potential risks and benefits: catheter retainment could potentially result in pro-longed symptoms and an increased risk of recurrence, while changing the catheter has risk of complications such as bleeding, fausse route, bacteremia and bladder spasms.

Participating takes 6 months in total. Within these 6 months, each patient will be phoned 8 times. Each consult takes approximally 10-15 minutes.

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

In order to participate in the trial, a patient must meet all of the following criteria:

1. Aged 18 years or older.
2. An indwelling catheter, either a transurethral or suprapubic catheter, that has been in place for at least 2 weeks.
3. At least one CAUTI-related symptom, defined according to the IDSA guideline: onset or worsening of fever (> 38 degrees), rigors, altered mental status, malaise or lethargy with no other identified cause, flank pain, costovertebral angle tenderness, acute haematuria, pelvic discomfort, or suprapubic pain/tenderness. In patients with spinal cord injury, increased spasticity, autonomic dysreflexia, or sense of unease are also compatible with CAUTI.
4. Urine culture with >= 103 colony-forming units (CFU)/mL of >= 1 bacterial species, or urine culture with <103 CFU/mL along with a positive blood culture with the same microorganism as the urine culture.
5. The ability to provide written informed consent for the use of their data.
6. Sufficient proficiency in the Dutch or English language, both spoken and written, to effectively communicate with the research team and accurately complete the questionnaires.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded

from participation in the trial:

1. Having an immunodeficiency: High-dose corticosteroid use (equivalent of >= 20 mg prednisolone per day for > 4 weeks), severe primary immunodeficiency, organ transplant, neutropenia (absolute neutrophil count < 0.50 x 10*/L)
2. Expiration of the indication of the indwelling catheter.
3. Having a planned (routine) catheter replacement during antibiotic therapy.
4. Contraindications for catheter replacement (judgement treating physician)
5. Kidney catheters (nephrostomy or double-J catheter).
6. Needing bladder irrigations because of gross haematuria.
7. Having bladder stones.
8. Female patients who are pregnant.
9. Having a life expectancy of < 3 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-03-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL88486.058.25