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Bladder irrigation with tap water to reduce antibiotic treatment for catheter-associated urinary tract infections

Submission date
17/04/2024

Recruitment status
No longer recruiting

Registration date
17/04/2024

Overall study status
Completed

Last Edited
13/03/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Catheter-associated urinary tract infection (CAUTI) is a common complication among patients performing clean intermittent catheterization (CIC) or with an indwelling catheter (IDC) and is often treated with antibiotics. With increasing rates of antibiotic resistance and healthcare costs, it is necessary to explore alternatives for antibiotic treatment of CAUTIs which are cost-effective, well tolerated by patients and lead to less antibiotic resistance. This is the first study to prospectively evaluate the safety and effectiveness of bladder irrigation (BI) with tap water to reduce antibiotic use for the treatment of CAUTIs in patients with urinary catheters in the community setting. In addition, health-related quality of life (QoL) and treatment satisfaction are evaluated.

Who can participate?
Patients aged 18 years old and over with an indwelling catheter performing CIC and recurrent CAUTI symptoms

What does the study involve?
Bladder irrigation (BI) with tap water is prescribed for patients experiencing recurrent catheter-associated urinary tract infection (CAUTI) symptoms, excluding systemic symptoms like fever, flank pain, or delirium. Symptoms include cloudy or strong-smelling urine, hematuria, dysuria /pain during catheterization, urinary frequency, urinary urgency, and suprapubic pain. Patients will receive BI instructions from continence nurses at the outpatient clinic. For the procedure, a 50 ml catheter-tip syringe filled with tap water at body temperature is used. The bladder is actively irrigated by flushing and drawing back on the plunger to reduce bacterial concentration. This process repeats until the outgoing solution is clear, indicating a lack of contamination. A tapering schedule is employed for BI, resumed upon recurrent CAUTI symptoms. Patients are advised to contact their physician and halt BI if systemic symptoms arise. Antibiotics are prescribed when BI is infeasible, insufficient in relieving symptoms, or for CAUTI with systemic symptoms.

What are the possible benefits and risks of participating?
The possible benefits to participation are less antibiotic use and fewer CAUTIs. The possible risks include performing time-consuming procedures (BI) and more CAUTIs.

Where is the study run from?
Erasmus University Medical Center

When is the study starting and how long is it expected to run for?
November 2021 to February 2024

Who is funding the study?
Erasmus University Medical Center

Who is the main contact?
Mrs Felice van Veen, f.vanveen@erasmusmc.nl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Bladder irrigation with tap water to reduce antibiotic treatment for catheter-associated urinary tract infections: a prospective observational study

Acronym
TAP-UTI

Study objectives
This study aims to evaluate patient-reported outcomes on the safety and effectiveness of BI with tap water to reduce antibiotic use for the treatment of CAUTI in patients performing clean intermittent catheterization (CIC) or with an indwelling catheter (IDC) in the community setting.

Additionally, the study will look at the quality of life and treatment satisfaction of BI with tap water. It is hypothesized that BI with tap water helps reduce the use of antibiotics in the treatment of CAUTIs while not increasing the risk of developing a CAUTI with systemic symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/12/2021, METC Erasmus MC (Dr. Molewaterplein 40, Rotterdam, 3015 GD, Netherlands; +31 (010) 704 0 704; metc@erasmusmc.nl), ref: EMC-2021-0855

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community, Hospital

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Bladder irrigation (BI) with tap water to reduce antibiotic use for the treatment of catheter-associated urinary tract infection (CAUTI) in patients with urinary catheters in the community setting

Interventions

Bladder irrigation (BI) with tap water will be prescribed to patients with recurrent catheter-associated urinary tract infection (CAUTI) symptoms and is used for the treatment of CAUTIs without systemic symptoms (e.g. fever, flank pain or delirium). CAUTI symptoms include cloudy or strong-smelling urine, hematuria, dysuria/pain during catheterization, urinary frequency, urinary urgency and suprapubic pain. Patients will receive BI instructions from our continence nurses at the outpatient clinic.

For the BI procedure, a 50 ml catheter-tip syringe is used, which is filled with tap water (at body temperature) from a clean, non-sterile container. The bladder is actively irrigated by flushing in and drawing back on the plunger to reduce the concentration of bacteria in the bladder. This procedure is repeated until the outgoing solution is clear, and thus without contamination. A tapering schedule is used for BI, which is resumed upon recurrent CAUTI symptoms. Patients are instructed to contact their physician and discontinue BI in the presence of systemic symptoms. Antibiotics are prescribed when BI is not feasible, does not sufficiently relieve CAUTI symptoms or in case of a CAUTI with systemic symptoms.

Intervention Type
Procedure/Surgery

Primary outcome measure
The number of self-reported antibiotic treatments for catheter-associated urinary tract infections (CAUTIs) during 3 months, measured using a self-developed questionnaire at baseline and 3-months follow-up

Secondary outcome measures
The following secondary outcome measures will be assessed at baseline and 3-months follow-up:
1. Number of self-reported CAUTIs during 3 months measured using a self-developed questionnaire
2. Health-related quality of life measured using the EuroQoL EQ-5D-5L
3. Treatment satisfaction measured using the Treatment Satisfaction Questionnaire for Medication-9 items (TSQM-9)

Overall study start date
01/11/2021

Completion date
25/02/2024

Eligibility

Key inclusion criteria
1. Patients with an indwelling catheter performing CIC
2. Recurrent CAUTI symptoms for which BI started

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
58

Total final enrolment
60

Key exclusion criteria
1. Received BI with tap water solely for other reasons, such as prevention of catheter blockage or bladder stones, or treatment of hematuria
2. A history of surgical bladder reconstruction

Date of first enrolment
01/07/2022

Date of final enrolment
20/02/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus University Medical Center
Dr. Molewaterplein 40
Rotterdam
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3015 GD

Sponsor information

Organisation
Erasmus MC

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
https://www.erasmusmc.nl/nl-nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Universitair Medisch Centrum Rotterdam

Alternative Name(s)
Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Erasmus MC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewd journal

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Mrs Felice van Veen, f.vanveen@erasmusmc.nl.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/10/2024	13/03/2025	Yes	No