Single use vs reusable catheters in intermittent CatheterizatiOn for treatment of urinary retention: a Multicenter, Prospective, RandomizEd controlled, non-inferiority trial.

No registrations found.

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

Summary

ID

NL-OMON19999

Source
Nationaal Trial Register

Brief title
COMPaRE

Health condition

Urinary retention due to non-neurogenic and neurogenic causes

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: This trial is funded by ZonMw ‘Goed gebruik hulpmiddelenzorg’ project 853001104 and by the Erasmus MC Efficiency grant 2019-19112.

Intervention

Outcome measures

Primary outcome

The main objective of this trial is to determine whether reusable catheters are not less safe as single use catheters, measured by symptomatic UTIs.

Secondary outcome

Secondary objectives are adverse events like hospital admissions due to UTIs, changes in urine cultures/urinary microbiome, urethral damage/strictures, kidney/bladder stone formation and quality of life of the participants. Cost effectiveness and recommendations for practice will be provided.

Study description

Background summary

Clean intermittent catheterization (CIC) is the treatment of choice for patients suffering from non-neurogenic (idiopathic) or neurogenic urinary retention. Idiopathic retention is associated with over distension of the bladder after spinal or general surgery, bladder obstruction by enlarged prostate, pelvic surgery, but in most patients no cause is found. Spinal cord injury (SCI) and multiple sclerosis (MS) are important causes of neurogenic retention. Most patients catheterize four to six times a day, keeping the catheterized volume preferably below 400-500 ml. Virtually all patients on CIC in Europe utilize single use (=disposable) catheters, which is in contrast to the practice of the use of reusable catheters in many non-European countries. The available literature on the differences in safety and efficacy between single use and reusable catheters is conflicting. On the one hand, it has been suggested with in vitro experiments that reuse of catheters introduces unwanted bacterial contamination and therefore increases the risk of symptomatic urinary infections and other complications, like stone formation and urethral strictures. On the other hand, limited evidence in patients on CIC suggest that reusable catheters are not less safe and not less effective as disposable catheters.
The study will be performed in patients on CIC in a multicenter, prospective, randomized controlled, non-inferiority trial. The participants will be assigned to either single use or reuse catheterization during twelve months follow-up.
The main objective of this trial is to determine whether reusable catheters are not less safe as single use catheters, measured by symptomatic UTIs. Secondary objectives are adverse events like hospital admissions due to UTIs, changes in urine cultures, urethral damage/strictures, kidney/bladder stone formation and quality of life of the participants. Cost effectiveness and recommendations for practice will be provided.

Study objective

The hypothesis of this trial is that reusable catheters are as safe and efficient as single use catheters and will be cost-effective.

Study design

Time of inclusion: 18 months
Time of follow-up: 12 months consisting of 4 clinical visits where urine samples will be obtained and 5 telephone calls.

Intervention

Half of the participants will start using the reusable catheter after randomization. This catheter is developed for reuse and will be used for two weeks. The catheter will be stored in a container filled with a cleaning substance, which will be renewed every 24 hours. The control group will remain using their single use catheter. All participants will be followed for 12 months.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Male/Female patients ≥ 16 years old
- Diagnosed with urinary retention or significant post-void residue due to non-neurogenic or neurogenic causes
- Expected chronic, but at least for a duration of twelve months, necessity for daily drainage of the urinary bladder

- Be able to administer self CIC via the urethra daily and have at least two weeks of experience in CIC

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Age < 16 years
- Temporary use of catheterization because of transient causes
- Known significant urethral stricture which complicates CIC
- Urinary tract stones
- Bladder augmentation
- Non-urethral catheterization
- History of bladder cancer with active follow-up
- The use of immunosuppressives for transplantation or auto-immune diseases
- Neurocognitive disease which prevents complete comprehension of the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2020
Enrollment:	456
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

All IPD will be available that underlie results in our future publication beginning 9 months and 36 months after article publication. Researchers whom provide a methodologically sound proposal will receive a link to the database. The type of intended analyses is preferably meta-analysis of IPD. After 36 months the data will be available upon request without additional investigator support.

Ethics review

Positive opinion

Date:	14-01-2020
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	NL8296
Other	METC Erasmus MC : METC 2019-0134

Study results

Summary results

N/A