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

Published: 18-10-2019
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The main objective of this trial is to determine whether reusable catheters are not less efficient as single use catheters, measured by symptomatic UTIs. Secondary objectives are adverse events like hospital admissions due to UTIs, urethral damage/...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON54700

Source
ToetsingOnline

Brief title
COMPaRE

Condition

- Urinary tract signs and symptoms

Synonym
inability of bladder emptying, Urinary retention

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: - Bladder voiding dysfunction, - Intermittent catheterization, - Post void residue, - Single-use/multiuse catheter

Outcome measures

Primary outcome

The primary outcome is symptomatic urinary tract infections (UTIs).

Secondary outcome

Secondary outcomes will be other adverse events, like hospital stays due to UTIs, bladder stones and haematuria, and symptom specific and quality of life questionnaires. Quality of life will be measured by the following validated questionnaires: EQ-5D-5L and an adjusted (shortened) version of the ICIQ-UAB questionnaire. The ease of use of the catheters will be evaluated by the Patient Global Impression of Improvement (PGI-I) scale, the ISCQ and the InCaSaQ. Cost-effectiveness calculation on both types of catheters will be made. The economic evaluation will be done using the iMCQ and iPCQ questionnaires. Two additional questions concerning patients thoughts on environmental burden and healthcare costs will be asked at week 0 and week 52.

Study description

Background summary

Clean intermittent catheterization (CIC) is the treatment of choice for patients suffering from idiopathic or neurogenic urinary retention. Possible causes are enlarged prostate, pelvic surgery, spinal cord injury (SCI) or multiple sclerosis (MS). Most patients catheterize four to six times a day, keeping the catheterized volume preferably below 400-500 ml. Virtually all patients on CIC in the Netherlands utilize single use (=disposable) catheters, which is in contrast to the practice of the use of reusable catheters in many non-European countries. The main reason is that there exists thus far no CE marked reusable catheter. Our group has found that a Japanese company owns the CE mark and this will be used to introduce the reusable catheter in Europe. The suppliers who make the single use catheters support all patient advocate and continence nurse societies. The webpages of the industry suggests strongly that disposable catheters are less associated with urinary tract infections and other complications. In this context, it is relevant to note that the global urinary catheter market size was valued in 2015 at USD 3.4 billion, with gradual grow in future perspective. This market is formed for around 60% by disposable catheters. 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 research question of this study will be: Is the use of reusable catheters in patients on intermittent catheterization in urinary retention not less safe or not less efficient as the use of single use catheters?. The potential effects on the Dutch health economics will be provided. The project is supported by ZonMW (project 853001104 in the framework of Goed Gebruik Hulpmiddelenzorg).

Study objective

The main objective of this trial is to determine whether reusable catheters are not less efficient as single use catheters, measured by symptomatic UTIs. Secondary objectives are adverse events like hospital admissions due to UTIs, urethral damage/strictures, kidney/bladder stone formation and quality of life of the participants. Cost effectiveness and recommendations for practice will be provided.

Study design

The study will be performed in patients who CIC in a multicenter, prospective, randomized controlled, non-inferiority trial. The patients on CIC will be assigned to either single use or reuse catheterization during 12 months with the primary outcome "the amount of symptomatic UTIs". The total duration of this trial is 36 months.

Intervention

Patients will be randomized into two groups, one group will use the single use catheters, the other group will start using the reusable catheter which will be renewed every two weeks.

Study burden and risks

Patients will have an extension of two clinical visits at the hospital and seven telephone contacts for follow up of the trial. The extra burden for patients in the reusable catheter group is the cleaning procedure of the catheter in which patients will be schooled. During the follow-up, patients are asked to fill in the questionnaires four times.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Elderly (65 years and older)

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 prevents 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2020
Enrollment:	386
Type:	Actual

Medical products/devices used

Generic name:	Reusable catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-10-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	22-11-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL68597.078.19
Other	NL8296