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

Gepubliceerd: 14-01-2020 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19999

Bron
Nationaal Trial Register

Verkorte titel
COMPaRE

Aandoening

Urinary retention due to non-neurogenic and neurogenic causes

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: This trial is funded by ZonMw ‘Goed gebruik hulpmiddelenzorg’ project 853001104 and by the Erasmus MC Efficiency grant 2019-19112.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-01-2020
Aantal proefpersonen:	456
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

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.

Ethische beoordeling

Positief advies

Datum:	14-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8296
Ander register	METC Erasmus MC : METC 2019-0134

Resultaten

Samenvatting resultaten
N/A