Patient comfort assessment of the Femflow. A follow-up study of the validation of a new catheter for intermittent Self-Catheterization in female patients

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Primary Objective: This study is set up to validate the patient comfort of the current design of the FemFlow. For the validation of the patient comfort, the FemFlow will be rated on:Comfort during insertion Comfort of an alien object in the bladder...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON45287

Source
ToetsingOnline

Brief title
Patient comfort assessment of the Femflow

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Acontractile or underactive bladder dysfunction: inability to empty the bladder

Research involving
Human

Sponsors and support

Primary sponsor: Novuqare BV
Source(s) of monetary or material Support: Novuqare BV

Intervention

Keyword: incomplete bladder emptying, intermittent self-catheterization, lower urinary tract dysfunction

Outcome measures

Primary outcome

Comfort during insertion - quantitative assessment by participant

Comfort of FemFlow the bladder - quantitative assessment by participant

Comfort during urinating - quantitative assessment by participant

Comfort during removal of FemFlow - quantitative assessment by participant

Comfort of FemFlow for several body postures - quantitative assessment by participant

The primary objectives will be rated with a questionnaire, using a 1-10 scale.

The questions are set up to rate comfort; 1 represents *extremely uncomfortable* and 10 represents *extremely comfortable*. The question must score 6 or higher to be assessed as acceptable. The average outcome of the main study parameters shall score 7 or higher.

Secondary outcome

Secondary study parameters/endpoints.

No mucosa damage.

Cystoscopic investigation.

Study description

Background summary

Patients suffering from lower urinary tract dysfunction such as neurogenic bladder dysfunction (caused by e.g. spinal cord injury, cerebrovascular disease, Parkinson*s disease) and bladder retention (caused by e.g. urethral obstruction, neurological disease, unknown causes) or taking medication that affects the contractility of the detrusor muscle commonly have voiding difficulties. These difficulties can be: obstructed voiding, incomplete bladder emptying or complete urinary retention. As a result patients may suffer from urgency/frequency or Urge Urinary Incontinence, nocturia and the risk of recurrent urinary tract infections (UTIs), bladder stones and eventually renal insufficiency. Intermittent self-catheterization (ISC) has become the golden standard for the treatment of patients with obstructed voiding, incomplete bladder emptying and urinary retention. The International Continence Society defines ISC as the use of a technique to drain the bladder with subsequent removal of the catheter, which is performed by the patient itself. ISC provides better symptom management and reduces incontinence episodes and UTIs. Furthermore it greatly improves Quality of Life (QoL) by increasing the patients* confidence and independence, resulting in greater freedom to participate in daily and social activities. ISC is favored over an indwelling catheter because it has various health advantages such as a lower risk on UTIs and kidney infections and better self-management. Patient compliance or adherence, described by the World Health Organization as the extent of which a person*s behavior corresponds with agreed recommendations from a health care professional, is of large influence on the success and Quality of Life of the patient. Partial or no adherence to the ISC recommendations can result in major urological complications. The barriers for adherence can be divided into two main factors. The first is patient related and dependent on physical disabilities and psychological factors such as (fear for) pain during ISC. The second is related to external factors such as access to public toilets, inadequate facilities in public toilets and availability of appropriate catheters and assistance appliances, quality of teaching and training for ISC. Various types of catheters exist: Coated or pre-lubricated, hydrophilic-coated or uncoated (with separate lubrication) which come in different lengths and shapes. The most commonly used are disposable and used only once. The choice for the type of catheter depends on the functional and cognitive ability of the patient, but also on the ease of use (opening the package and manipulation), package discretion and costs. Another disadvantage of common used catheters is that they are disposables and therefore used only once. Current ISC catheters need to be inserted every micturition, because they are disposable.

Furthermore, when applying objects through the urethra several times a day, this may cause mucosa irritation. To overcome these problems in female patients, the FemFlow has been developed. The FemFlow is a new type of catheter which is inserted and removed only once per day. Once inserted into the bladder, the patient can empty the bladder simply by pulling a cord at any point in time. The FemFlow will then expand which will open the urethra, allowing the bladder to be emptied. The current development stage of the FemFlow is *proof of principle*. The FemFlow is operated as follows: I. Insertion into the bladder via the urethra (once a day). II. Pull the cord for emptying the bladder, let go of the cord when bladder is empty (may be repeated multiple times a day). III. Remove FemFlow by pulling the removal cord (once a day).

Study objective

Primary Objective: This study is set up to validate the patient comfort of the current design of the FemFlow. For the validation of the patient comfort, the FemFlow will be rated on:

Comfort during insertion
Comfort of an alien object in the bladder
Comfort during urinating
Comfort of FemFlow for several body postures
Comfort during removal of FemFlow

The primary objectives will be rated with a questionnaire.

Study design

Study procedures
All patients will receive a patient information letter and will be fully instructed by the study investigator. After oral and written instructions patients have to give their approval by signing an Informed Consent form.

1. At the beginning of the patient visitation, the investigator shall start with the FemFlow research protocol.
2. The bladder will be checked for deformations and abnormalities of the mucosa or other factors that might influence the correct working of the FemFlow by urethra-cystoscopy. When any abnormalities are found, the research protocol will stop.
3. The FemFlow will be inserted into the bladder by or under the supervision of the Principle Investigator. The patient is asked several questions about the comfort of insertion of the FemFlow as part of a questionnaire.
4. The patient will be asked to drain the bladder twice within a 2-hour period by pulling the drain-cord. The patient will be required to remain in close proximity of the research facility during these 2 hours in case any assistance

of the Principle Investigator is required. That means that the patient is asked not to leave the hospital.
5. At the end of the visit, a questionnaire will be handed over to the patient for them to fill in after each draining session. The patient is asked several questions about the comfort of the FemFlow in the bladder during sitting, standing and supine position.

Study burden and risks

Investigation takes 3 hours.
Possible mucosale damage during insertion of extraction of the FemFlow.
Possible hinder if cystoscopic removal is needed.

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

- Age 18-80 years
- Woman on CIC who cannot empty the bladder themselves (so no incomplete voiders)
- Patient has signed a written Informed Consent form
- Patient is free of uncontrolled psychiatric illness
- Patient is free of urinary tract infection
- is the patient free of urethral strictures, trauma of necrosis?

Exclusion criteria

- Patients with large deviations in urethra or bladder caused by anatomical defects, earlier surgery or caused by other damage of the pelvic floor.
- Patients with a urinary tract infection, or a history of urinary tract infections.
- Patients who can urinate themselves, or on partial Clean Intermittent Catheterization
- Morbid obesity (BMI > 40 kg/m2)
- Patients with hematuria and/or blood clots in the urine

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Bladder catheter
Registration:	No

Ethics review

Approved WMO Date:	11-01-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL60587.100.17