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# Urinary catheter valve feasibility study

**Submission date**
27/01/2020

**Recruitment status**
No longer recruiting

**Registration date**
31/01/2020

**Overall study status**
Completed

**Last Edited**
31/01/2020

**Condition category**
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
A urinary catheter is a flexible tube used to empty the bladder and collect urine in a drainage bag. A urinary catheter is usually used when people have difficulty urinating naturally. Indwelling catheters (IDC) remain in place for many days or weeks, and are held in position by an inflated balloon in the bladder. The bladder normally 'fills' with urine and then 'flushes' when it is emptied. This does not happen with the use of an indwelling urinary catheter that continually drains and it is thought that might affect the tone of the bladder or increase the risk of blockage and infections. The fill and flush urinary catheter valve has been developed to automatically open once the bladder has filled.

The fill and flush valve (valve) is an automated valve which is designed to open in response to rising bladder pressure which occurs as the bladder becomes full. The valve is situated between the IDC and the drainage bag as a manual valve would be.

The objective of this study is to assess preliminary safety, effectiveness, reliability, comfort and user acceptability of the valve with adults who have a long-term IDC and the feasibility of undertaking future community-based evaluation.

Who can participate?
Patients aged 18 years or older, with an IDC who use a standard manual valve or use a drainage bag with free drainage.

What does the study involve?
Participants will need to attend the clinic on two occasions for a whole day. During the test days, participants will test the valve during sitting, standing, and walking, after drinking specified amounts of fluid.

What are the possible benefits and risks of participating?
Benefits - The immediate benefit is that participants will be able to test a new catheter valve, that if successful they might be able to use in the future. In the long term, the results from the study may provide a fill and flush valve for urinary catheter users that meets their needs and may prove to increase bladder tone and reduce urinary tract infections.
Risks - During the testing there is the potential for participants to experience some leakage of urine or some abdominal discomfort as the bladder fills. Disconnecting the catheter tube from

the catheter bag frequently is considered to increase the risk of urinary tract infection. For the purposes of the study, the additional disconnection is undertaken during two study visits.

Where is the study run from?
Southampton NIHR Clinical Research Facility (UK)

When is the study starting and how long is it expected to run for?
January 2020 to October 2020

Who is funding the study?
NIHR Central Commissioning Facility (CCF) (UK)

Who is the main contact?
Dr Cathy Murphy
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Cathy Murphy

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
245818

### ClinicalTrials.gov number
NCT04243902

### Secondary identifying numbers
CPMS 40193, IRAS 245818

# Study information

## Scientific Title
Urinary catheter ‘fill and flush’ valve: safety, effectiveness, acceptability and feasibility trial

## Study objectives
The fill and flush valve is an automated valve which is designed to open in response to rising bladder pressure which occurs as the bladder becomes full. It is hypothesised that the benefit of the valve is this could overcome the problems cited above by ensuring optimal bladder filling followed by swift urine drainage and flushing of the catheter and drainage bag lumen thereby also reducing the risk of biofilm formation and blockage.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 21/05/2019, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44(0)207 104 8107; NRESCommittee.EastofEngland-CambridgeCentral@nhs.net), ref: 19/EE/0158

## Study design
Interventional non-randomised study

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Urinary catheterization

## Interventions
This study a ‘first in human’ assessment of reliability, effectiveness, comfort and user acceptability with 16 long-term catheter users.

This study will be in one phase over 6 months, and comprise of 2 groups:
Group 1 - The valve will initially be tested in 8 participants who currently use a standard manual valve (without leg-bag). Such participants (and their bladders) will be accustomed to the filling and emptying of the bladder with an indwelling urinary catheter (IDC) in situ and therefore represent the most predictable and safest population on which to test the valve.
This first group will include a safety cohort of participants (n=4). All safety data will be reviewed

from the initial 4 participants before further participants can undergo the study investigation. Review of the initial data will include an interim safety report submission to the Medicines and Healthcare products Regulatory Agency (MHRA) in line with the issued Notice of No Objection. Once all relevant permissions to proceed have been granted, the valve will then be tested in the remainder of standard manual valve participants (n=4) to complete Group 1.
Group 2 - The valve will then be tested with participants (n=8) who currently use a drainage bag with free drainage in order to test the valve with people who are no longer accustomed to the process of filling and emptying the bladder (Group 2).

Each participant will attend two visits (up to a maximum of 7 hours per day) at the Southampton NIHR Clinical Research Facility testing the valve.

We will recruit 16 long-term IDC users (8 who currently use a standard manual valve e.g. a 'flip-flo' – with or without an attached drainage bag- and 8 who use just a drainage bag).

Local GP practices will be invited to act as Participant Identification Centres (PIC) sites. This will be supported by Wessex Clinical Research Network.

In each case, the potential recruits will be asked to contact the research team directly (providing their contact details) if they wish to find out more about the study. Potential participants will be sent a Participant Information Sheet (PIS). This will be followed up (no sooner than 24 hours after they have received the PIS) with a phone call to discuss the study, answer any questions and check eligibility. Those who wish to participate, who have not been identified by their GP, will then be sent a form to obtain their written consent for the research team to contact their GP for a letter of confirmation of health status and potential eligibility to participate in study. The participant must personally sign and date the latest approved version of the informed consent form before any clinical investigation specific procedures are performed.

Participants will be required to give signed informed consent at the first visit to the Clinical Research Facility where they will be provided with a copy of the signed consent form.

Day 1 – Non-ambulatory testing
Pre-testing:
• Confirm eligibility, answer any questions and ask participant to confirm consent.
• First drink (250mls) provided.
• Record demographic data on CRF (date of birth, address, telephone number, ethnicity, GP address).
• Take baseline observations: blood pressure, temperature, pulse and respiratory rate.
• Participant completes Quality of Life tools: EQ-5D-5L and Long-term Catheter Quality of Life Tool.

Testing Procedure:
With the participant sitting (except when transferring to and lying on the bed for bladder scanning):
1. Participant puts on pad with pants to secure it in place
2. Record participant's self-reported bladder sensations
3. Scan bladder and record volume in Valve Log
4. Research nurse fits the lowest pressure valve according to manufacturer's instructions for use and attach a drainage bag for urine collection
5. Record participant's self-reported bladder sensations in valve log
6. Scan bladder and record volume in valve log
7. If the valve remains open with urine draining freely, replace with the next level pressure valve

(up to 3 valves) until free drainage has ceased and the valve remains closed
8. Participant to lie on bed for hourly bladder scanning until bladder volume is >400mls or the participant experiences bladder discomfort or the valve automatically opens. Record participant' s bladder sensations before each scan and:
8.1. If the volume is >400mls or the participant is experiencing discomfort
8.1.1. Ask the participant to contract abdominal muscles, press down on abdomen or bear down as if trying to pass urine to increase bladder pressure.
8.1.2. If the valve opens, proceed as below (b).
8.1.3. If the valve does not open, disconnect the valve, attach a new drainage bag and allow the bladder to drain. Stop the trial for that participant.
8.2. If the valve automatically opens:
8.2.1. Record the amount of urine voided
8.2.2. Scan the bladder for any residual volume
9. If the valve has opened with a urine volume of less than 500ml, repeat process 7 & 8 at 1 hourly intervals for 5 hours. If the valve did not open before bladder volume reached 500ml, stop testing at this point.

Participants will be requested to drink a minimum of 500mls of fluids over the first two hours, then a minimum of 150mls for the next 3 hours. They will be given a choice of drinks. After testing has ended for that day, participants will be given a new manual valve and/or drainage bag as per usual use.

Valve Questionnaire: Each day, after all testing is completed, participants will complete a Valve Questionnaire to assess the valve for comfort.

On Day 2, the above will be repeated, with a check of any changes to eligibility made beforehand. The participant will also be asked to stand, walk around and cough at specific intervals.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Urinary catheter 'fill and flush' valve

## Primary outcome measure
1. Valve opening - Proportion of observations of automatic valve opening before bladder capacity (500ml or less) is reached - as measured by bladder scanner during the study
2. Bladder emptying - proportion of valve voids with residual urine <100ml – as measured by bladder scanner during the study

## Secondary outcome measures
1. User acceptability as measured by the valve self-report questionnaire at end of Day 2
2. Quality of life as measured by EQ-5D-5L and Long-term Catheter Quality of Life Tool at baseline

## Overall study start date
20/11/2018

### Completion date
30/03/2020

## Eligibility

### Key inclusion criteria
1. IDC-users (urethral or suprapubic), over 18, who have had a catheter in situ for at least one month and use a manual valve or drainage bag to collect urine
2. Independent with catheter care needs (e.g. bag emptying or valve opening)
3. Able to transfer from bed to chair, stand and walk short distances unaided
4. Able to drink moderate levels of fluid (500mls in the first 2 hours and 150mls per hour thereafter)
5. Able to provide informed consent (self-report and research nurse assessment)
6. Usual medical provider provides confirmation of suitability

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 16; UK Sample Size: 16

### Key exclusion criteria
1. End stages of a terminal illness
2. Current treatment of urinary tract infection
3. Has been advised by a urologist against using a valve on clinical grounds
4. Lack of bladder sensation (e.g. unable to sense when bladder needs emptying)
5. Previous bladder surgery that could affect the integrity of the bladder
6. At known risk of autonomic dysreflexia

### Date of first enrolment
03/02/2020

### Date of final enrolment
30/03/2020

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Southampton General Hospital
University of Southampton and University Hospital Southampton NHS Foundation Trust
Tremona Road
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## Sponsor information

### Organisation
University of Southampton

### Sponsor details
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### Sponsor type
Hospital/treatment centre

### Website
http://www.southampton.ac.uk/

### ROR
https://ror.org/01ryk1543

## Funder(s)

### Funder type
Government

### Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: II-LB-0216-20002

### Funder Name
National Institute for Health Research (NIHR) (UK)

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
Planned publications as follows:
• Peer reviewed scientific journals
• Internal report
• Conference presentation
• Publication on website
• Submission to regulatory authorities

### Intention to publish date
30/11/2021

### Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary
Other

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | version v3.1 | 20/08/2019 | 31/01/2020 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |