ISRCTN42028483 https://doi.org/10.1186/ISRCTN42028483

MultICath: A multicentre randomised controlled trial comparing mixed catheter management (combination of multi- and single-use) vs single-use catheter management by intermittent catheter users over 12 months

Submission date
27/08/2019

Recruitment status
No longer recruiting

Registration date
05/09/2019

Overall study status
Completed

Last Edited
18/10/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The MultICath trial is about finding out whether people who use intermittent catheterisation (IC) to empty their bladder experience no more urinary tract infections reusing some of their catheters than they would using their standard care single-use catheters.
Intermittent catheterisation is commonly used by people who have difficulty emptying their bladder because of bladder muscle weakness or nerve diseases. Intermittent catheterisation is generally a very useful way to empty the bladder as it avoids having to have a catheter in all the time and protects the bladder and kidneys from further damage.

Who can participate?
People over the age of 18 who are currently carrying out intermittent catheterisation.

What does the study involve?
We hope to recruit 578 participants. 50% of these participants will be randomised to using single-use catheters (usual care) with the other half randomised to the mixed-use strategy whereby participants will use a combination of single-use and multi-use catheters for 12 months. Participants in the mixed-use arm will use a reusable silicone catheter which CE marked for reuse for some of their intermittent catheterisation.

Participants who consent and are randomised to the trial will be asked to complete a series of questionnaires about their catheter use and any urinary tract infections (UTIs) experienced over the course of the trial in addition to their general health. Participants will also be required to provide regular urine specimens at specific time points and anytime the participant suspects a UTI.

What are the possible benefits and risks of participating?
By taking part, participants will be helping researchers to gather information and improve their understanding about intermittent catheterisation with multi-use catheters. Participants will be under closer follow-up than usual and may learn more about intermittent catheterisation from the information will give you during the trial.
It is possible that participants might experience a UTI, but this is a risk with all catheter use. There is not enough research evidence at the moment to be sure that the infection risk from multi-use catheters is not worse than single-use catheters and that is why we are doing the trial. Some participants allocated to mixed-use catheter management might experience some discomfort or skin soreness when testing Cliny catheters, which is also a risk with all catheter use. Researchers will be gathering participants feedback about this throughout the trial.

Where is the study run from?
University fo Southampton, UK

When is the study starting and how long is it expected to run for?
November 2019 to July 2025

Who is funding the study?
The study has been funded with an NIHR Programme Grant for Applied Research.

Who is the main contact?
Prof Mandy Fader
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Study website
https://www.southampton.ac.uk/multicath/index.page

Contact information

Type(s)
Scientific

Contact name
Prof Mandy Fader

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
252496

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42679

Study information

Scientific Title
A non-inferiority randomised controlled trial to compare mixed (multi/single-use) catheter management with single-use catheter management by intermittent catheter users over 12 months

Acronym
MultICath

Study objectives
The use of a combination of single-use and multi-use catheters for participants carrying out intermittent catheterisation is no worse than in terms of the incidence of UTIs if only single-use catheters were used

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/07/2019, South Central - Hampshire A Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8210; hampshirea.rec@hra.nhs.uk), ref: 19/SC/0334

Study design
Randomized; Both; Design type: Treatment, Device, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Urinary tract infection

Interventions
Current intervention as of 22/07/2022:
The researchers hope to recruit 578 participants who are carrying out intermittent catheterisation from around the UK. 50% of these participants will be randomised to using single-use catheters (usual care) with the other half randomised to the mixed-use strategy whereby participants will use a combination of single-use and multi-use catheters for 12 months. Participants in the mixed-use arm will use a reusable silicone catheter which CE marked for reuse for some of their intermittent catheterisation.). Randomisation will be administered centrally by a secure web-based randomisation system. Permuted random blocks of variable length will be used to allocate participants 1:1 to the mixed-use and single-use only groups.

Participants who consent and are randomised to the trial will be asked to complete a series of questionnaires about their catheter use and any urinary tract infections (UTIs) experienced over the course of the trial in addition to their general health. Participants will also be required to provide regular urine specimens at specific time points and anytime the participant suspects a UTI.

Schedule of Events
Visit 1- Screening and baseline (face to face visit):
- Written informed consent from participant taken by appropriately delegated member of the research team.
- Eligibility confirmed and documented.
- Baseline activities completed- patient medical history taken, concomitant medication, baseline and randomisation CRF completed, Barthel index calculated and EQ-5D-5L completed.
-Urine sample taken and sent to central laboratory
- Participant randomisation to single-use IC or mixed-use IC strategy.

Revisions to the protocol have been made, to minimise face-to-face contact - the patient can choose to receive the informed consent form by post, the kit is then posted to the participant and instructions/guidance are given, and monthly contacts carried out, by phone or videoconference.

Two-week learning period:
Participants in both the single-use and mixed-use IC strategy will participate in two-week learning period.
For participants randomised to the mixed-use strategy, participants will be provided Cliny catheters and cleaning items and taught how to use the multi-use Cliny catheters.

Two-week learning period (both arms)
- provision of event diary
-provision of catheter use 7 day diary
- AE/SAE assessment by research team
(Participants to complete diaries as an aide-memoire during two week learning period).

Monthly contact (telephone follow up for up to 12 months)
- Completion of monthly questionnaire with participant by research team.
- AE/SAE check by research team.
- Participant completion of 7-day catheter use diary and event diary

-Assessment of compliance (mixed-use arm only)
- As required, provision of Cliny catheters and products required for re-use (mixed-use arm only)

6-Month contact
In addition to the monthly questionnaire, AE/SAE assessment, assessment of compliance, the 6 month visit will
require completion of the following:
- 6 month questionnaire with participant by research team. 6 month questionnaire consists of the Intermittent Self-Catheterization Questionnaire (ISC-Q) and questions around patient costs.
- Health utilisation questionnaire
- EQ-5D-5L questionnaire
-Urine sample taken and sent to central laboratory

12-Month contact (EoS visit)
In addition to the monthly questionnaire, AE/SAE assessment and assessment of compliance, the EoS visit will also consist of completion of the following:
-EoS questionnaire with participant by research team. EoS questionnaire consists of the Intermittent Self-Catheterization Questionnaire (ISC-Q) and questions around patient costs.
- Health utilisation questionnaire
- EQ-5D-5L questionnaire
-Urine sample taken and sent to central laboratory

At the time of UTI event, participant to complete and return:
- Urine sample (sent to central laboratory)
- UTI questionnaire (sent to Newcastle Trials Unit)

Optional: Semi-structured interview
Up to 40 participants from the mixed-use IC strategy will be approached to consent and participate in a semi-structured qualitative interview.

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Previous intervention:
The researchers hope to recruit 520 participants who are carrying out intermittent catheterisation from around the UK. 50% of these participants will be randomised to using single-use catheters (usual care) with the other half randomised to the mixed-use strategy whereby participants will use a combination of single-use and multi-use catheters for 12 months. Participants in the mixed-use arm will use a reusable silicone catheter which CE marked for reuse for some of their intermittent catheterisation.). Randomisation will be administered centrally by a secure web-based randomisation system. Permuted random blocks of variable length will be used to allocate participants 1:1 to the mixed-use and single-use only groups.

Participants who consent and are randomised to the trial will be asked to complete a series of questionnaires about their catheter use and any urinary tract infections (UTIs) experienced over the course of the trial in addition to their general health. Participants will also be required to provide regular urine specimens at specific time points and anytime the participant suspects a UTI.

Schedule of Events
Visit 1- Screening and baseline (face to face visit):
- Written informed consent from participant taken by appropriately delegated member of the research team.
- Eligibility confirmed and documented.

- Baseline activities completed- patient medical history taken, concomitant medication, baseline and randomisation CRF completed, Barthel index calculated and EQ-5D-5L completed.
-Urine sample taken and sent to central laboratory
- Participant randomisation to single-use IC or mixed-use IC strategy.

Two week learning period:
Participants in both the single-use and mixed-use IC strategy will participate in two week learning period.
For participants randomised to the mixed-us strategy, participants will be provided Cliny catheters and cleaning items and taught how to use the multi-use Cliny catheters.

Two week learning period (both arms)
- provision of event diary
-provision of catheter use 7 day diary
- AE/SAE assessment by research team
(Participants to complete diaries as an aide-memoire during two week learning period).

Monthly contact (telephone follow up from up to 12 months)
- Completion of monthly questionnaire with participant by research team.
- AE/SAE check by research team.
- Participant completion of 7-day catheter use diary and event diary
-Assessment of compliance (mixed-use arm only)
- As required, provision of Cliny catheters and products required for re-use (mixed-use arm only)

6-Month contact
In addition to the monthly questionnaire, AE/SAE assessment, assessment of compliance, the 6 month visit will
require completion of the following:
- 6 month questionnaire with participant by research team. 6 month questionnaire consists of the Intermittent Self-Catheterization Questionnaire (ISC-Q) and questions around patient costs.
- Health utilisation questionnaire
- EQ-5D-5L questionnaire
-Urine sample taken and sent to central laboratory

12-Month contact (EoS visit)
In addition to the monthly questionnaire, AE/SAE assessment and assessment of compliance, the EoS visit will also consist of completion of the following:
-EoS questionnaire with participant by research team. EoS questionnaire consists of the Intermittent Self-Catheterization Questionnaire (ISC-Q) and questions around patient costs.
- Health utilisation questionnaire
- EQ-5D-5L questionnaire
-Urine sample taken and sent to central laboratory
-Participants to return remaining Cliny catheters and unwanted products used for reuse to research team (mixed-use arm only).

At the time of UTI event, participant to complete and return:
- Urine sample (sent to central laboratory)
- UTI questionnaire (sent to Newcastle Trials Unit)

Optional: Semi-structured interview
Up to 40 participants from the mixed-use IC strategy will be approached to consent and participate in a semistructured qualitative interview.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 18/10/2024:
The occurrence of at least one episode of Microbiologically Confirmed Symptomatic Urinary Tract Infection with Help-seeking/Self-help behaviour (MCS-UTI+HS) over the 12-month follow-up period, defined by the following criteria:
1. Presence of Symptoms: At least one new or worsening sign or symptom from the trial symptom set or other symptoms reported by the participant
2. Help-seeking/Self-help Behaviour: The participant seeks help and/or treatment from a GP, researcher, or other healthcare professional, or implements their self-help strategy (e.g., increasing fluid intake, self-administration of antibiotics)
3. Microbiological Confirmation: A single catheter urine specimen during a symptomatic episode shows 103 colony-forming units (cfu)/mL of 1 bacterial species, either before or after starting antibiotic treatment.

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Previous primary outcome measure as of 22/07/2022 to 18/10/2024:
1. At least one episode over the 12-month follow-up period of Microbiologically Confirmed Symptomatic Urinary Tract Infection with Help-seeking behaviour (MC SH-UTI) defined as:
1.1. Presence of at least one sign or symptom (S; new or worsening; listed on the trial symptom set or other symptoms reported by the participant) AND
1.2. Help-seeking behaviour (i.e. participant seeks help and/or treatment from GP/researcher or other HCP or implements own self-help strategy e.g. increase fluid intake, self-administration of antibiotics) AND
1.3. 10(3) colony-forming units (cfu)/mL of ≥1 bacterial species in a single catheter urine specimen taken during a symptomatic episode before or after starting antibiotic treatment

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Previous primary outcome measure:
At least one episode over the 12 month follow-up period of Microbiologically Confirmed Symptomatic Urinary Tract Infection with Help-seeking behaviour (MC S UTI + H) defined as
- Presence of at least one sign or symptom (S; new or worsening; listed on the trial symptom set or other symptoms reported by the participant)AND
- Help-seeking behaviour (i.e. participant seeks help and/or treatment from GP/research nurse or other HCP or implements own self-help strategy e.g. increase fluid intake, self-administration of antibiotics)
AND
- 103 colony-forming units (cfu)/mL of 1 bacterial species in a single catheter urine specimen taken within the previous 48 h and taken during a symptomatic episode before or after starting antibiotic treatment.

Secondary outcome measures
Current secondary outcome measures as of 22/07/2022:
1. The number of MC SH-UTI over the 12-month follow-up measured as an incidence rate
2. At least one episode over the 6-month follow-up period of microbiologically confirmed symptomatic urinary tract infection with help-seeking behaviour (MC SH-UTI) as defined for the primary outcome
3. The number of MC SH-UTI over the first 6 months of follow-up measured as an incidence rate
4. Antibiotic use: Rate per month of prescription of antibiotics for presumed S-UTI (with or

without meeting MC SH-UTI definition above) during the 12-month period as reported by the monthly questionnaire. This will also be examined over the first 6 months of follow-up.
5. Haematuria: Rate per month and proportion of 6-monthly urine samples meeting criteria of micro haematuria defined as >10/ml RBC as reported from routine urine sample during the 12-month follow-up. This will also be examined over the first 6 months of follow-up.
6. Urethral bleeding: Rate per month of visible urethral bleeding during 12-month follow-up period as reported via monthly questionnaire. This will also be examined over the first 6 months of follow-up.
7. User quality of life (QoL): QoL recorded by ISC-Q (Pinder tool) at 6 and 12 months. The Pinder tool reports on single-use catheter only. A modified version for reporting on multi-use catheters will be used for mixed-use strategy. A weighted average of the two score completions will be used for the intervention (mixed-use) group: the weights will reflect the proportion of time catheters were used as single and multi-use.
8. Health status recorded by the EQ-5D-5L questionnaire
9. Proportion of participants expressing preference for one or other catheter management strategy (mixed or single-use only) in the intervention arm at 6 and 12 months as measured by the 6-month and end-of-study (EoS) questionnaire
10. Costs of managing multi-use catheters versus single-use only. Measured by prescription of catheters, support and training received for the mixed package vs single-use catheters assessed using the unit costs for NHS resources based on representative national sources (NHS reference costs, units cost of Health and Social Care, 2003, Lesley Curtis).
11. To determine if a strategy of intermittent urinary catheter mixed-use is no worse than a strategy of intermittent urinary catheter single-use for outcomes of cost-effectiveness. Measured by UTI, monthly and health service utilisation questionnaire. Participants' use of health care services related to IC, and S-UTIs will be based on self-reporting via the UTI questionnaire completed whenever a UTI is suspected and also during the monthly telephone follow-ups.
12. Treatment costs will be based on the number of health professional consultations, tests and prescriptions recorded

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Previous secondary outcome measures:
1. The number of MC SH-UTI over the 12 month follow-up measured as an incidence rate
2. At least one episode over the 6 month follow-up period of microbiologically confirmed symptomatic urinary tract infection with help-seeking behaviour (MC S-H UTI) as defined for the primary outcome
3. The number of MC SH-UTI over the first 6 months of follow-up measured as an incidence rate
4. Antibiotic use: Rate per month of prescription of antibiotics for presumed S-UTI (with or without meeting MC S-H UTI definition above) during the 12 month period as reported by the monthly questionnaire. This will also be examined over the first 6 months of follow up
5. Haematuria: Rate per month and proportion of 6-monthly urine samples meeting criteria of micro haematuria defined as > 40 RBC s/Ml as reported from routine urine sample during the 12-month follow-up. This will also be examined over the first 6 months of follow-up
6. Urethral bleeding: Rate per month of visible urethral bleeding during 12 month follow-up period as reported via monthly questionnaire. This will also be examined over the first 6 months of follow-up
7. User quality of life (QoL): QoL recorded by ISC-Q (Pinder tool) at 6-months and 12 months. The Pinder tool reports on single-use catheter only. A modified version for reporting on multi-use catheters will be used for mixed-use strategy. A weighted average of the two score completions will be used for the intervention (mixed-use) group: the weights will reflect the proportion of time catheters were used as single and multi-use

8. Health status recorded by the EQ-5D-5L questionnaire at baseline, 3-months, 6-months and 12-months
9. Proportion of participants expressing preference for one or other catheter management strategy (mixed or single-use only) in the intervention arm at 6 months and 12 months as measured by the 6 month and End of study (EoS) questionnaire
10. Costs of managing multi-use catheters versus single-use only. Measured by prescription of catheters, support and training received for the mixed package vs single-use catheters assessed using the unit costs for NHS resources based on representative national sources (NHS reference costs, units cost of Health and Social Care, 2003, Lesley Curtis)
11. To determine if a strategy of intermittent urinary catheter mixed-use is no worse than a strategy of intermittent urinary catheter single-use for outcomes of cost-effectiveness. Measured by UTI, monthly and health service utilisation questionnaire. Participants' use of health care services related to IC, and S-UTIs will be based on self-reporting via the UTI questionnaire completed whenever a UTI is suspected and also during the monthly telephone follow-ups. Treatment costs will be based on the number of health professional consultations, tests and prescriptions recorded

Overall study start date
01/01/2018

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Adult men and women aged ≥18 years
2. Currently using IC (via the urethra), performed by self or sole carer
3. Patients who have been IC users for at least 6 weeks
4. Patients where IC planned to continue for >12 months and 2 weeks
5. Able and willing to adhere to a 12month follow up period
6. Patient has provided written informed consent for participation in the trial prior to any trial specific procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 578; UK Sample Size: 578

Total final enrolment

578

Key exclusion criteria
Current exclusion criteria as of 22/07/2022:
1. Aged <18 years
2. Use of IC for self- dilatation of urethral stricture without bladder drainage
3. Non-urethral route for catheterisation e.g. Mitrofanoff
4. Use of less than one catheter per day or seven per week
5. External, non-sole carer required for IC (i.e. where sterile technique and catheter is required e.g. visiting community nurse performs IC)
6. Inability to give informed consent or have primary outcome information collected
7. Employee or relation of employee of a manufacturer or distributor of IC catheters
8. Women who report they are pregnant or who plan to become pregnant during the trial
9. Participation in another trial
10. Patients in the terminal stage of an illness

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Previous exclusion criteria:
1. Age < 18 years
2. Use of IC for self- dilatation of urethral stricture without bladder drainage
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5. Inability to give informed consent or have primary outcome information collected
6. Employee or relation of employee of a manufacturer or distributor of IC catheters
7. Women who report they are pregnant or who plan to become pregnant during the trial
8. Participation in another trial
9. Patients in the terminal stage of an illness

Date of first enrolment
10/02/2021

Date of final enrolment
12/07/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
University of Southampton
Health Sciences Building 67
University Road
Southampton

United Kingdom
SO17 1BJ

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-Trym
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BS10 5NB

Study participating centre
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Sponsor information

Organisation
University of Southampton

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0610-10078

Results and Publications

Publication and dissemination plan
The researchers plan to publish the study results in peer reviewed journal after the trial ends. The researchers also plan to publish a protocol paper

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
Anonymised data from this study may be available subject to regulatory and ethical approval in line with the Newcastle Clinical Trials Unit data-sharing policy (https://www.ncl.ac.uk/nctu/work-with-us/data-sharing/). Request for data should be directed to the corresponding author.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary	28/06/2023	No	No