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Randomised controlled trial comparing the clinical and cost-effectiveness of various washout policies versus no washout policy in preventing catheter-associated complications in adults living with long-term catheters

Submission date
04/11/2019

Recruitment status
Stopped

Registration date
06/11/2019

Overall study status
Stopped

Last Edited
08/04/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims

Urinary catheters are soft tubes put into the bladder to drain and then collect urine. In the UK, an average of 1 in 1000 people use long-term indwelling catheters. People using these catheters can experience complications, like blockages (where the urine does not drain into the catheter bag properly), urinary infections, pain, and a type of incontinence called catheter bypass. These complications can affect a person's quality of life. They may also mean more emergency visits with nurses and GPs. Research shows that people consider blockage to be one of the most troubling aspects of using catheters over a long period. In current standard catheter care, catheter blockages are dealt with by either changing the catheter more often and/or using catheter washout liquids to washout the catheter. Some people are advised to do a catheter washout every week to try to reduce blockages. Others are not. The difference is because at present, there is no clear evidence to show whether doing regular washouts helps avoid blockages. People doing washouts also use different solutions. One is a weak salty (saline) solution, and the other is a citric mix, more like weak lemon juice. Both solutions are used in the NHS but it is not known which works best. The aim of this study is to find out the best way to reduce the number of blockages that can happen in people who have long-term indwelling catheters to find out if washing out the catheter every week using catheter washout liquids reduces catheter blockages and other problems like urinary incontinence or urinary tract infections.

Who can participate?

Adult men and women who have been using a catheter for ≥ 28 days and for whom there is no plan for discontinuation of catheter use at the time of recruitment, who are able to or has someone who can do catheter washouts for them.

What does the study involve?
Participants are randomly allocated to one of three groups for 24 months:
1. Weekly normal saline catheter washouts plus standard care
2. Weekly acidic (citric) catheter washouts plus standard care
3. Standard care only (i.e. no catheter washouts)
Participants are given a special calendar to record any problems with their catheter. They are contacted each month by a member of the research team who asks about any catheter-related problems they may have had. Every six months, participants are asked to complete a questionnaire about their quality of life and satisfaction with treatment.

What are the possible benefits and risks of participating?
Participants will receive the same level of care from their healthcare team whether or not they take part in the study. Participants may not benefit personally from taking part, but will be directly helping us to improve the care of patients with a long-term catheter in the future.
The washout solutions used in the study are already being used in the NHS. There may be a possible increase in the risk of urine infection when doing regular catheter washouts. The researchers will monitor this closely within the study and will ask participants about urine infections during every follow-up in the study. There are some side effects from the long-term use of catheters but the researchers do not think that the risk will be increased by introducing regular washouts.

Where is the study run from?
University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
October 2019 to September 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Lynda Constable
l.constable@abdn.ac.uk

Study website
https://w3.abdn.ac.uk/hsru/CatheterII

Contact information

Type(s)
Scientific

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Scientific

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Aberdeen
United Kingdom
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
259559

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 41284, IRAS 259559

Study information

Scientific Title
Randomised controlled trial comparing the clinical and cost-effectiveness of various washout policies versus no washout policy in preventing catheter-associated complications in adults living with long-term catheters

Acronym
CATHETER II

Study objectives
In the UK, it is estimated that approximately 1 in 500 people live with a long term catheter. A urinary catheter is a thin, soft, flexible tube inserted into the bladder to drain urine to a collection bag. LTCs can be associated with complications including catheter blockage and urinary tract infections. Catheter blockages affect 50% of people with LTCs. Blockage and infection can impact upon quality of life and NHS resources.

There are two broad strategies for preventing and managing catheter blockage: more frequent change of catheter and/or the use of liquid solutions to washout or flush the catheters. We do not know enough about the benefits, harms or costs of regular prophylactic washouts, to recommend whether or not they should be standard care.

In this study the researchers will determine the clinical and cost-effectiveness, acceptability, satisfaction, and safety of weekly prophylactic catheter washout policies in addition to standard LTC care compared to standard LTC care only for adults living with LTC. The primary outcome is catheter blockage requiring intervention. The primary economic outcome is the incremental cost per quality adjusted life year (QALY) gained for each washout policy compared to standard LTC care only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/03/2019, Wales REC6 (Health and Care Research Wales) (Wales National Pool, Sketty Lane, Swansea SA2 8QG; Tel: +44 (0)1267 611164, 01874 615949; Email: Wales.REC6@wales.nhs.uk), ref: 19/WA/0015

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

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Community

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
Catheter-associated complications

Interventions
The researchers are recruiting 600 people who have a LTC from primary care, secondary care and care homes. They are randomising participants to one of three groups:
1. Saline washouts. A policy of weekly prophylactic normal saline catheter washouts plus standard LTC care
2. Acidic washouts. A policy of weekly prophylactic acidic (citric) catheter washouts plus standard LTC care
3. Standard LTC care only (i.e. no prophylactic catheter washouts)

The researchers are following participants for 24 months to assess catheter blockages, infections, and complications, plus their quality of life, satisfaction, costs to the participant and NHS. They are exploring the views, attitudes, experiences and expectations of washouts with participants, nurses, and doctors.

Intervention Type
Procedure/Surgery

Primary outcome measure
Any catheter blockage requiring intervention up to 24 months post randomisation, from the question 'Have you had any catheter blockages since we last spoke to you?' from patient-reported monthly phone call CRF (monthly for 24 months) (Intervention is defined as any of the following: unplanned catheter removal or change or washout performed by the participant/ designated person or required unplanned visits to/from any healthcare provider, or hospital admission)

Secondary outcome measures
Current secondary outcome measures as of 22/04/2022:
1. S-CAUTI requiring antibiotics use from the questions 'Have you had a urine infection since we last spoke to you?' and 'How many infections required antibiotics?' from patient-reported monthly phone call CRF (monthly for 24 months)
2. Duration of LTC in situ, catheter change due to other reasons than blockage, discontinuation of LTC use; from the questions 'Has there been discontinuation of long-term catheter use?', 'For the (reported problem), what treatment did you have?' and Answers 'Catheter change' from patient-reported monthly phone call CRF (monthly for 24 months)
3. Adverse events; where participant has reported a treatment in the patient-reported monthly phone call CRF (monthly for 24 months) and the question of the clinical team is asked 'Is this a

SAE? Please tick'
4. Hospital admissions, GP/nurse outpatient visits for catheter-related complications from the questions 'Since we last spoke to you, have you had to stay in hospital overnight for any of the problems related to your catheter?', 'For the (reported problem), where did you have treatment or a consultation with a doctor or nurse?' and possible answers 'GP at home, Nurse at home, care home staff, GP at surgery, Nurse at practice, Self/informal carer, Staff at hospital' from patient-reported monthly phone call CRF (monthly for 24 months)
5. Generic quality of life assessed by EQ-5D-5L17 (EuroQol questionnaire – 5 dimensions – 5 levels) patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation
6. Condition-specific quality of life assessed by ICIQ-LTCqol18 (International Consultation on Incontinence Modular Questionnaire – Long Term Catheter quality of life) patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation
7. Adherence to allocated interventions,events changing type and/or frequency (or cessation) of catheter washouts in arms A and B and rates of commencing on prophylactic washouts in arm C; from the questions 'Have you done a weekly washout since we last called you ?', 'Have you had any problems with the weekly washout?', 'Has your clinical care team recommended a change in washout frequency?', 'Has your clinical care team recommended a change in type of washout solution?' and 'Have you done any regular (preventative) washouts since we last called you?' from patient-reported monthly phone call CRF (monthly for 24 months)
8. Patients' convenience and satisfaction assessed by an adapted version of the abbreviated Treatment Satisfaction Questionnaire for medication; Timepoint(s): 0,6,12,18,24 months post-randomisation patient-reported questionnaire
9. Impact on day to day activities using the General Self-Efficacy Scale (GSE)20 and ICECAP-A (ICEpop CAPability measure for Adults) (≤ 65 years) or ICECAP-O21 (ICEpop CAPability measure for Older people) > 65 years patient-reported questionnaire; Timepoint(s): 0, 6, 12, 18, 24 months post-randomisation
10. Time and travel costs for patients and their relatives, friends or informal carers, from patient-reported questionnaire questions 'We wish to know how much money and time were spent by you and any companion in attending health care appointments or being admitted to hospital', including travel costs, time and whether or not accompanied by another person.; Timepoint(s): 18 months post-randomisation

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2. Duration of LTC in situ, catheter change due to other reasons than blockage; from the questions 'Has there been discontinuation of long-term catheter use?', 'For the (reported problem), what treatment did you have?' and Answers 'Catheter change' from patient-reported monthly phone call CRF (monthly for 24 months)
3. Adverse events; where participant has reported a treatment in the patient-reported monthly phone call CRF (monthly for 24 months) and the question of the clinical team is asked 'Is this a SAE? Please tick'
4. Hospital admissions, GP/nurse outpatient visits for catheter-related complications from the questions 'Since we last spoke to you, have you had to stay in hospital overnight for any of the problems related to your catheter?', 'For the (reported problem), where did you have treatment or a consultation with a doctor or nurse?' and possible answers 'GP at home, Nurse at home, care home staff, GP at surgery, Nurse at practice, Self/informal carer, Staff at hospital' from patient-reported monthly phone call CRF (monthly for 24 months)
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7. Adherence to allocated interventions; from the questions 'Have you done a weekly washout since we last called you ?', 'Have you had any problems with the weekly washout?', 'Has your clinical care team recommended a change in washout frequency?', 'Has your clinical care team recommended a change in type of washout solution?' and 'Have you done any regular (preventative) washouts since we last called you?' from patient-reported monthly phone call CRF (monthly for 24 months)
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Overall study start date
01/10/2018

Completion date
14/09/2023

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Catheter has been in-situ for ≥28 days
3. No plan for discontinuation of LTC at the time of recruitment
4. Able to undertake catheter washouts or has a designated person able to perform washouts
5. Able to complete the trial documentation or has a proxy able to complete the trial documentation
6. Any type and route of LTC can be included

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600

Total final enrolment
80

Key exclusion criteria
Current participant exclusion criteria as of 22/04/2022:
1. Intermittent self-catheterisation
2. Pregnant or contemplating pregnancy
3. Spinal cord injury at or above the sixth thoracic vertebra (T6) (risk of Autonomic Dysreflexia - AD)
4. Ongoing S-CAUTI (until treatment is complete)
5. Visible hematuria (unless investigated/ treated)
6. Known allergies to either of the catheter washout solutions
7. Current bladder cancer (until treatment is complete and patient discharged from cancer surveillance program)
8. Known bladder stones (until treatment is complete)
9. Unable to provide consent due to incapacity
10. Any other clinical and social reasons that would be deemed by the recruitment team to be unsuitable for the study

If a participant stops using a long-term catheter (no catheter in situ) >=28 days. All data collected up to the point of stopping long term catheter use are retained and used in the analysis

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1. Intermittent self-catheterisation
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If a participant stops using a long-term catheter (no catheter in situ) >=28 days. All data collected up to the point of stopping long term catheter use are retained and used in the analysis

Date of first enrolment
01/12/2019

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Nursery Park
Nursery Road
Ashington
United Kingdom
NE63 0HP

Study participating centre
West Rainton Surgery
Woodland View
West Rainton
Houghton-le-Spring
United Kingdom
DH4 6RQ

Study participating centre
Great Lumley Surgery
Front Street
Great Lumley
Chester-le-Street
United Kingdom
DH3 4LE

Study participating centre
The Haven Surgery
The Haven
Burnhope
United Kingdom
DH7 0BB

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
The Chalgrove & Watlington Surgeries
Hill Road
Watlington
Oxford
United Kingdom
OX49 5AF

Study participating centre
Aneurin Bevan University Health Board
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
St Bartholomew's Medical Centre
Manzil Way
Cowley Road
Oxford
United Kingdom
OX4 1XB

Study participating centre

Summertown Health Centre
160 Banbury Road
Oxford
United Kingdom
OX2 7BS

Study participating centre
Priory Gardens Surgery
The Health Centre
Church St
Dunstable
United Kingdom
LU6 3SU

Study participating centre
Gosford Hill Medical Centre
167 Oxford Road
Kidlington
Oxford
United Kingdom
OX5 2NS

Study participating centre
Cwm Taf Morgannwg University Health Board
Royal Glamorgan Hospital
Ynysmaerdy
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Derbyshire Community Health Services NHS Foundation Trust
Trust Hq, Ash Green Disability Ctr
Ashgate Road
Ashgate
Chesterfield
United Kingdom
S42 7JE

Study participating centre

Bicester Health Centre
Coker Close
Bicester
United Kingdom
OX6 7AT

Study participating centre
Ashgate Medical Practice
Ashgate Road
Chesterfield
United Kingdom
S40 4AA

Study participating centre
Royal Primary Care Chesterfield
The Grange Family H/ctr
Stubbing Road
Grangewood
Chesterfield
United Kingdom
S40 2HP

Study participating centre
Royal Primary Care Clay Cross
Eldon Street
Clay Cross
Chesterfield
United Kingdom
S45 9NR

Study participating centre
Temple Sowerby Medical Practice
Linden Park
Temple Sowerby
Penrith
United Kingdom
CA10 1RW

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Willerby Hill

Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
Aspatria Medical Group
West Street
Aspatria
Wigton
United Kingdom
CA7 3HH

Study participating centre
Leadgate Surgery
George Ewen House
Watling Street
Leadgate
Consett
United Kingdom
DH8 6DP

Study participating centre
Vauxhall Health Centre
111-117 Limekiln Lane
Vauxhall
Liverpool
United Kingdom
L5 8XR

Study participating centre
Swanage Medical Practice
Railway Station Approach
Swanage
United Kingdom
BH19 1HB

Study participating centre
Chilwell Valley and Meadows Practice
Chilwell Meadows Surgery

Ranson Road
Chilwell
Nottingham
United Kingdom
NG9 6DX

Study participating centre
Midlands Partnership NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
St Francis Surgery
Pilgrims Close
Valley Park
Chandlers Ford
Southampton
United Kingdom
SO53 4ST

Study participating centre
Hockley Farm Medical Practice
39 Hockley Farm Road
Braunstone
Leicester
United Kingdom
LE3 1HN

Study participating centre
Wellbrook Medical Centre
Welland Road
Hilton
Derby
United Kingdom
DE65 5GZ

Study participating centre

Banbury Cross Health Centre
South Bar House
6 Oxford Road
Banbury
United Kingdom
OX16 9AD

Study participating centre
Pelton & Fellrose Medical Group
Unit 1, the Lavender Centre
Pelton Lane
Pelton
Chester Le Street
United Kingdom
DH2 1HS

Study participating centre
The Shirley Health Partnership
Shirley Health Centre
Grove Road
Shirley
Southampton
United Kingdom
SO15 3UA

Study participating centre
Highcliffe Medical Centre
Heila House
Lymington Road
Highcliffe
Christchurch
United Kingdom
BH23 5ET

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Church Street Practice
The Health Centre
Mably Way
Grove
Wantage
United Kingdom
OX12 9BN

Study participating centre
Derby Road Health
336 Derby Road
Nottingham
United Kingdom
NG7 2DW

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Manchester University Hospital NHS Ft (hq)
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre

The White Horse Medical Practice
The Faringdon Medical Centre
Volunteer Way
Faringdon
United Kingdom
SN7 7YU

Study participating centre
Mendip Vale Medical Practice (yatton)
155 Mendip Road
Yatton
Bristol
United Kingdom
BS49 4ER

Study participating centre
Brierley Park Medical Centre
127 Sutton Road
Huthwaite
Sutton-in-ashfield
United Kingdom
NG17 2NF

Sponsor information

Organisation
NHS Grampian

Sponsor details
-
-
Scotland
United Kingdom
AB15 6RE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes:

Results and Publications

Publication and dissemination plan
The protocol will be publicly available on the study website and the NIHR HTA website. The researchers intend to publish the study protocol as soon as practicable.

Updated 08/08/2022:
The protocol has been published on 4th August 2022 and is available at https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-022-06577-2

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
A request to access the datasets generated during the trial should be directed in the first instance to the corresponding author (Professor Mohamed Abdel-fattah, m.abdelfattah@abdn.ac.uk). The datasets collected in questionnaires at all timepoints and the baseline, monthly and serious adverse event case report forms for all 80 participants recruited to the trial are available. The dataset is available in fully anonymised electronic form, at an individual level, and in accordance with participant consent. The data dictionaries, study protocol, statistical analysis plan, patient information leaflets and template case report forms are also available on request to facilitate interpretation of data. Questionnaire templates, or parts thereof, may be available pending review of the relevant licensing agreements. Data for the study is currently available within a local repository at the University of Aberdeen and will be retained for a period of at least 10 years after close of trial in accordance with funder, Sponsor and local archiving procedures. Applicants will require to complete a data request form, which will be reviewed by a Data Sharing Committee which includes the Chief Investigator. Applications will be considered on a case-by-case basis from bonafide researchers. We are obligated to ensure that optimal use is made of the data that is collected for research and we recognise the value of sharing individual level data. The interests of research participants, researchers and other stakeholders will be considered when considering each application. A fully authorised data sharing agreement will be required prior to the release of data.

IPD sharing plan summary
Available on request

Study outputs

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

Protocol article		04/08/2022	05/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		02/12/2024	03/12/2024	Yes	No
Other publications	Embedded longitudinal qualitative study	07/04/2025	08/04/2025	Yes	No