

The MultiCath Study

Submission date 09/03/2016	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 10/03/2016	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 12/08/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Intermittent ('in-out') catheterisation is a technique used by people who have difficulty emptying their bladder. It involves a thin tube being passed into the bladder via the urethra (the tube through which urine passes) so that the urine in the bladder can be drained when needed (intermittently). Traditionally, intermittent catheters could be cleaned and reused, often for several days or longer (multi-use catheters). Since then, catheters have been developed that are intended to be used once only and then thrown away (single-use). Most people in the UK use single-use catheters now and multi-use catheters are not readily available any more. One of the most common complications of intermittent catheterisation is that users often develop urinary tract infections, UTIs (water infections). Many believe that using multi-use catheters is more likely to cause UTIs, however there is little research supporting this claim. The aim of this study is to find out whether using a mixture of multi-use catheters and single-use catheters (mixed-use) is just as safe as using only single-use catheters, and whether it is acceptable to users.

Who can participate?

Patients aged 16 and over, who are currently using or are planning to use intermittent catheterisation for the next 12 months.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are asked to use single-use catheters only over a course of 12 months. Those in the second group are asked to use a mixture of multi-use and single-use catheters for the same length of time. Participants in this group are taught about safe catheter cleaning and storage techniques. Once a month during the study, participants are interviewed by a research nurse over the telephone about any UTI symptoms experienced in the past month. At the end of the study, the amount of UTIs experienced by patients in each group is compared.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

University College London (UK)

When is the study starting and how long is it expected to run for?
March 2016 to March 2017

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

Who is the main contact?
1. Ms Margaret Macaulay (public)
2. Dr Alexander von Wilamowitz-Moellendorff (scientific)

Study website
<http://www.southampton.ac.uk/multicath/index.page>

Contact information

Type(s)
Public

Contact name
Ms Margaret Macaulay

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United Kingdom
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Type(s)
Scientific

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United Kingdom
NE2 4AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Development and Clinical Trial of a Mixed (Multi/Single-use) Catheter Management Package for Users of Intermittent Catheterisation (The MultiCath Study)

Acronym

MultiCath

Study objectives

The aim of this study is to find out whether using a mixture of single-use and multi-use catheters is acceptable to users and no more likely to cause urinary tract infection or other problems than using single-use catheters only.

Ethics approval required

Old ethics approval format

Ethics approval(s)

15/SC/0433

Study design

Multi-centre randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

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

Topic: Primary Care, Renal; Subtopic: Primary Care (Renal Disorders), Renal (Renal Disorders); Disease: All Diseases, All Renal Disorders

Interventions

Participants are randomly allocated to one of two groups.

Group 1: Participants use a mixture of single-use and multi-use catheters for 12 months.

Group 2: Participants use single-use catheters only for 12 months.

Intervention Type

Other

Primary outcome measure

Symptomatic urinary tract infection rate rate is measured over 12 months through monthly telephone interviews.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2016

Completion date

31/03/2017

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility**Key inclusion criteria**

1. Aged 16 years and over
2. Intermittent catheterisation planned to continue for 12 months
3. Able and willing to adhere to a 12-month follow up period
4. Currently using or preparing to start using intermittent catheterisation (via the urethra), performed by self or sole carer
5. Patient has provided written informed consent for participation in the study prior to any study specific procedures

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria

1. Aged below 16 years
2. Use of IC for self-dilatation of urethral stricture (ISD) without bladder drainage
3. Non-urethral route for catheterisation e.g. Mitrofanoff
4. External carer required for IC (i.e. where sterile technique and catheter is required e.g. visiting

community nurse performs IC)

5. Inability to give informed consent or have primary outcome information collected

6. Women who are pregnant, planning to become pregnant or breast feeding during the trial

Date of first enrolment

01/03/2016

Date of final enrolment

31/03/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

Department of Medicine Clerkenwell building

Archway Campus

2-10 Highgate Hill

London

United Kingdom

N19 5LW

Sponsor information

Organisation

University of Southampton

Sponsor details

University Road

Southampton

England

United Kingdom

SO17 1BJ

Sponsor type

University/education

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

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

Not provided at time of registration

Intention to publish date

31/03/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No