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# The MultICath Study

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 09/03/2016 | Stopped | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 10/03/2016 | Stopped | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/08/2019 | Urological and Genital Diseases | [_] 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)

# Contact information

### Type(s)
Public

### Contact name
Ms Margaret Macaulay

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University of Southampton
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### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Protocol serial number
20506

# 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

### Study type(s)
Treatment

### 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(s)
Symptomatic urinary tract infection rate rate is measured over 12 months through monthly telephone interviews.

### Key secondary outcome(s))
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 years

### Sex
All

### 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
United Kingdom

England

### 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

**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

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |