ISRCTN68472863 https://doi.org/10.1186/ISRCTN68472863

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)

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

Contact information

Type(s)
Public

Contact name
Ms Margaret Macaulay

Contact details
University of Southampton
Southampton
United Kingdom
-

Type(s)
Scientific

Contact name
Dr Alexander von Wilamowitz-Moellendorff

Contact details
Newcastle University
Newcastle Clinical Trials Unit
1-4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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