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# Clinical and cost-effectiveness of alternative urinary catheter design

**Submission date**
01/06/2022

**Recruitment status**
No longer recruiting

**Registration date**
07/06/2022

**Overall study status**
Completed

**Last Edited**
14/02/2023

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
A catheter is a flexible hollow tube, which is passed into the bladder to drain urine. In this study, we will be comparing 2 types of catheters (the Foley catheter and the Optitip catheter) to determine whether the Optitip catheter provides a clinically and cost-effective alternative to the traditional 'Foley' style catheter for reducing catheter associated urinary tract infection (CAUTI) and other complications for community-dwelling (own home or residential care) adults requiring long-term urinary urethral catheterisation.

Who can participate?
Adult long-term indwelling urethral catheter users who have experienced one or more catheter-associated UTIs in the last 12 months.

What does the study involve?
Participants will be randomly allocated to one of two groups. In addition to usual care, participants will either be assigned to an optitip catheter or foley catheter (control). Participants will be given the assigned catheter at their next planned catheter change and will continue to receive the assigned catheter (Optitip or Foley) for 12 months in addition to all other catheter-related care. Participants will be asked to fill out a diary with any occurrence of UTIs in the past month, any other symptoms that they think could be caused by their catheter, and any catheter changes they had. They will also be asked to fill out questionnaires and express their experiences using the Optitip catheter and taking part in the trial.

What are the possible benefits and risks of participating?
Participants may see a reduction in symptoms associated with long-term catheter use and will be helping to further our knowledge of other benefits of the Optitip catheter (if any) that may benefit other catheter users in the future. However, a possible risk is that the study catheter may not improve the participant's catheter-related symptoms. Participants will need to complete data collection calls/visits at baseline, and monthly throughout the trial, which they would not do if they were not taking part in the study.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run?
From September 2021 to November 2024

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

Who is the main contact?
Dr. Susanne Renz, cadet@soton.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Prof Catherine Murphy

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# Additional identifiers

### Integrated Research Application System (IRAS)
316989

### National Institute for Health and Care Research (NIHR)
131172

### Protocol serial number
HTA -

# Study information

### Scientific Title
Multicentre trial of the clinical and cost-effectiveness of a novel urinary catheter design in reducing catheter-associated urinary tract infection compared with the traditional Foley design for adults requiring long-term catheterisation

### Acronym
CaDeT

### Study objectives

To determine whether the Optitip catheter provides a clinically and cost-effective alternative to the traditional 'Foley' style catheter for reducing symptomatic catheter-associated urinary tract infection (CAUTI) and other complications for community dwelling adults requiring long-term urinary urethral catheterisation.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 15/11/2022, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverly Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG; +44 (0)7814 764 241; Ruth.Fraser4@nhslothian.scot.nhs.uk), ref: 22/SS/0094

## Primary study design
Interventional

## Study design
Multicentre randomized controlled superiority trial with two parallel arms, incorporating an internal pilot

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Urethral catheter-associated urinary tract infection

## Interventions
Participants will be randomly allocated to receive either the intervention or control catheter design at their next planned catheter change and will continue to receive the assigned catheter (Optitip or Foley) for 12 months in addition to all other standard catheter-related care. Patients will be randomised in a 1:1 ratio through a web-based system using a minimisation algorithm incorporating a random element to either the intervention or control. Factors used for minimisation will be gender, use of prophylactic antibiotics at baseline, and Trust/Partnership. Patients will be informed of allocation prior to their next catheter change.
Intervention: 12 months' use of the Optitip novel catheter design.
Control: 12 months' use of the Foley catheter design.

## Intervention Type
Device

## Phase
Phase III

## Drug/device/biological/vaccine name(s)
Foley catheter, Optitip catheter

## Primary outcome(s)
Clinical effectiveness of the Optitip catheter versus standard Foley catheter design measured using the incidence of symptomatic UTIs reported in patient diaries at a 6, 9, and 12 months

### Key secondary outcome(s)
1. Clinical effectiveness of the Optitip catheter versus standard Foley catheter design at reducing catheter-related issues, including unplanned catheter change and impact on quality of life measured using the catheter related quality of life at 12 months
2. Cost-effectiveness of the Optitip catheter compared to the standard 'Foley' catheter design measured using economic evaluation performed at a 12 months
3. Patient/carer and healthcare professional experience, and the acceptability of the Optitip catheter design measured using health-related quality of life and EQ-5D-5L questionnaires at a 3, 6, 9, and 12 months

### Completion date
30/11/2024

## Eligibility

### Key inclusion criteria
1. Aged ≥18 years
2. Community-dwelling (own home or residential care, including assisted living)
3. Use of an indwelling urethral catheter (for any reason) for ≥28 days and anticipated to continue with catheterisation for ≥1 year
4. Experienced one of more catheter-associated UTIs in the last 12 months
5. Willing to be randomised to either study arm
6. Willing and able to give informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Current therapy for bladder cancer
2. Under surveillance follow-up for previous bladder cancer
3. Current interventional therapy for prostate cancer
4. Previous bladder radiotherapy
5. Unresolved urethral stricture or bladder neck stenosis
6. Traumatic hypospadias
7. Terminally ill
8. Otherwise deemed unsuitable for trial

### Date of first enrolment

09/01/2023

**Date of final enrolment**
09/01/2024

# Locations

**Countries of recruitment**
United Kingdom

England

Scotland

**Study participating centre**
**Bradford District Care NHS Foundation Trust**
New Mill
Victoria Road
Saltaire
Shipley
United Kingdom
BD18 3LD

**Study participating centre**
**Norfolk Community Health and Care NHS Trust**
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

**Study participating centre**
**NHS Lanarkshire**
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

**Study participating centre**
**Hertfordshire Community NHS Trust**
Unit 1a Howard Court
14 Tewin Road
Welwyn Garden City

United Kingdom
AL7 1BW

**Study participating centre**
**Shropshire Community Health NHS Trust**
Shropshire County Pct
William Farr House
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XL

**Study participating centre**
**NHS Fife**
Hayfield House
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

# Sponsor information

**Organisation**
University Hospital Southampton NHS Foundation Trust

**ROR**
https://ror.org/0485axj58

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. Individual investigators may not publish data concerning their patients that are directly relevant to questions posed by the trial until the Trial Management Group (TMG) has published its report. The TMG will form the basis of the Writing Committee and advise on the nature of publications.

### IPD sharing plan summary
Published as a supplement to the results publication

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |