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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

Study website
https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/cadet.page

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
316989

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
IRAS 316989, HTA - NIHR131172

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

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

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 contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
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

Overall study start date
01/09/2021

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
310

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
England

Scotland

United Kingdom

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

Sponsor details
SGH, Level E, Laboratory & Pathology Block, SCBR, MP 138
Tremona Road

Southampton
England
United Kingdom
SO16 6YD
+44 (0)23 8120 4989
researchmanagement@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nhs.uk/Services/clinics/MapsAndDirections/DefaultView.aspx?id=113691

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Data from all centres will be analysed together and published as soon as possible. Planned publication of results in a high-impact peer-reviewed journal. Planned publication of protocol in a peer-review journal.

Intention to publish date
30/11/2025

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