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First-in-human testing of the Flume urinary catheter (a tube inserted to remove urine)

Submission date	Recruitment status	[X] Prospectively registered
11/02/2022	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/02/2022	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/01/2023	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A urinary catheter is a flexible tube used to empty the bladder and collect urine in a drainage bag.
The study is a first-in-human study of the “Flume” bladder catheter. The Flume catheter is a new type of indwelling catheter (a catheter that is left in place continuously) and is designed to prevent many of the risks associated with the current long-term indwelling catheters available on the market. The design of the Flume catheter aims to reduce irritation of the bladder, reduce infection rates and improve bladder drainage. Initial laboratory tests of the Flume catheter have demonstrated better drainage and resistance against infection compared to the most frequently used catheter, the Foley catheter (data in-house). The Flume catheter also offers the benefit that placement, retention and connections use the same approaches as the Foley design, so will be familiar to users and health care professionals.

Who can participate?
Adults over 18 years, who need an indwelling catheter.

What does the study involve?
The study will consist of three (3) sequential stages for established and new catheter users, who fulfil the eligibility criteria.
Stage 1 will undertake first-in-human testing to evaluate the short-term use and safety of the new Flume Catheter in 10 patients in a hospital setting.
Stage 2 will evaluate 15 long-term catheter users using a Flume catheter instead of a Foley catheter for one month at their usual residence (“home”), with regular follow-up.

What are the possible benefits and risks of participating?
The benefit of participating in the study is the opportunity to trial a new catheter design(the Flume catheter) that potentially could reduce irritation of the bladder, reduce infection rates and improve drainage of urine from the bladder compared to the most frequently used catheter, the Foley catheter. The risks of participating in the study are that the catheter does not drain urine from the bladder as well as the Foley catheter and there may be some comfort issues with the new catheter design.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2021 to November 2022

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
261189

Central Portfolio Management System (CPMS)
50458

Protocol serial number
PB-PG-0317-20026

Study information

Scientific Title
A new urinary catheter designed to improve bladder drainage: first-in-human testing of the FLUME catheter. Version 1.0

Study objectives
To confirm catheter function of the Flume catheter by determining ease of placement and removal; bladder drainage and that the catheter remains indwelling while in-situ
To investigate the incidence of adverse events associated with the Flume catheter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2021, Health & Social Care Research Ethics Committee A (Office for Research Ethics Committee Northern Ireland (ORECNI) (Business Services Organisation, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 9536 1407; RECA@hscni.net), ref: 21/NI/0150

Primary study design
Interventional

Study design
Interventional non randomized

Study type(s)
Treatment

Health condition(s) or problem(s) studied
A new urinary catheter designed to improve bladder drainage

Interventions
The study is a non-randomised, prospective trial of the new Flume urinary catheter.

The aims and objectives of the study are to evaluate the safety, tolerability and ease of use of the reconfigured “Flume catheter” in vivo. Prior to any study treatment or assessments taking place each subject will provide written informed consent. The study consists of 2 sequential stages for established and new catheter users, who fulfil the eligibility criteria.

The first part of the study will be a first in human study to evaluate the short-term use of the Flume catheter in 10 subjects. Stage 1 will be divided into parts 1a and 1b. The participants in both parts 1a and 1b will be evaluated in the hospital setting (North Bristol Trust / NBT,) to assess the safety and the ability to place the Flume catheter during planned elective surgery on the lower urinary tract, to remove it on schedule per operative no later than 72 hours prior to discharge and to check basic catheter function.

Stage 1a: During Stage 1a five patients will have a Flume catheter placed and removed as an additional aspect during general anaesthetic cystoscopy (routine endoscopic bladder inspection).

Stage 1b: Subsequently, five patients (1b) will have the catheter placed in a urological operation for which an indwelling catheter is routinely used, and removed at the usual time post-operatively (less than 48 hours). To ensure data is collected for both males and females a minimum of two participants from each gender will be recruited into Stage 1b.

Stage 2 will evaluate the Flume Catheter at the patient's usual residence ("home"), under regular supervision. 15 long term catheter (LTC) users will use the Flume catheter instead of a Foley catheter for one month with weekly phone calls, or videoconference if the patient prefers.

Progression to the next stage of the study will only occur after analysis and review of the study data from the previous stage, followed by approval by an independent Study Steering Committee (SSC) (comprising an independent chair and representation from primary care, nursing, users / public and an independent statistician). Data from the study will be collected to guide the design of a subsequent comparative clinical study.

Data collected from the study will be compared to published data and may be used to support a CE mark application authorising the routine clinical use of the Flume catheter.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Ratings of catheter function from HCP questionnaire:
1.1. Ease of Placement – to be measured via a questionnaire completed by the HCP right after the procedure
1.2. Bladder drainage - to be measured via a questionnaire completed by the HCP right after the procedure
1.3. Remained in situ – to be measured via a questionnaire completed by the HCP right after the procedure
1.4. Ease of removal – to be measured via a questionnaire completed by the HCP right after the procedure
2. Proportion of patients reporting an adverse event associated with their catheter – information is collected onto a CRF by a Research nurse 7 days after the procedure

Key secondary outcome(s)
1. To identify any problems with the FLUME design and manufacture, resulting from its use, particularly if impacting safety – measured by the type and incidence of adverse events throughout the duration of the trial
2. Incidence of Device Deficiency (DD) with Serious Adverse Device Effect (SADE) and DD with Adverse Device Effect (ADE) – information is collected onto a CRF by a Research nurse 7 days after the procedure

3. HCP experience and feedback – collected via a qualitative interview (Only applies to Stage 2)
4. Participant experience and feedback – collected via a qualitative interview and via the completion of questionnaires: PGI; VAS; EQ-5D-L and ICIQ-LCTqol (only applies to Stage 2)

Completion date
10/11/2022

Reason abandoned (if study stopped)
Primary outcomes achieved. Device failed to meet primary outcomes 1.3 and 2 – adverse device events.

Eligibility

Key inclusion criteria
Stage 1
1. Adults (>=18 years) of either gender, who are willing to participate in the study and give their written informed consent.
2. Subjects who are due to undergo planned general anaesthetic cystoscopy (routine endoscopic bladder inspection) – stage 1a only.
3. Subjects who are due to undergo a urological operation for which an indwelling catheter is routinely used – stage 1b only.

Stage 2
1. Adults (>= 8 years) of either gender.
2. Patients who need an indwelling urinary catheter as a method of bladder drainage for at least one month.
3. Patients who are willing and able to participate in the study and give their written informed consent.
4. Established catheter users. (Defined as “had a Foley catheter for at least the last 6 months and anticipate continuing to use one for at least the next 3 months”).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
15

Key exclusion criteria

Stage 1
1. Catheter-associated UTI at time of assessment, according to National Healthcare Safety Network (NHSN) surveillance and clinical criteria. One re-screen per subject is allowed, once the infection has been treated, the patient is eligible for the study. (https://www.cdc.gov/nhsn/index.html)
2. Participants who are on systemic antibiotics within 48 hours prior to enrolment.
3. Patient with a known allergy to any of the materials used in the FLUME catheter.
4. Patient has urinary tract anatomic abnormality that would prevent placement of a standard Foley catheter.
5. Informed consent cannot be obtained (See Section 12 for assessment of capacity).
6. Patient is breast feeding or pregnant, confirmation that the women is not pregnant will be determined by [1] clear indication of menopause, [2] time since last menstruation or [3] confirmation of abstinence. Women of child-bearing age will be asked to perform a pregnancy test if applicable after obtaining their consent.
7. Patients who have undergone a TURP (Transurethral resection of the prostate) within the last 3 months.
8. Patients for whom a Fr14 sized dual lumen catheter would be inappropriate.

Stage 2
1. Catheter-associated UTI at time of assessment, according to National Healthcare Safety Network (NHSN) surveillance and clinical criteria. One re-screen per subject is allowed, once the infection has been treated, the patient is eligible for study. This will be recorded through self reporting of symptoms and/or prescribed antibiotics.
2. Participants who are on systemic antibiotics within 48 hours prior to enrolment.
3. Patient currently taking (or expected to take) more than a single dose of antibiotics for prevention of other infections during the catheter indwell period.
4. Suprapubic catheter user.
5. Patient with a known allergy to polyurethane or silicone used in the FLUME or comparator catheter.
6. Patient has urinary tract anatomical abnormality that would prevent placement of a standard Foley catheter.
7. Informed consent cannot be obtained.
8. Patient is unable or unwilling to comply with the study follow-up schedule.
9. Patient is breastfeeding woman or pregnant (confirmation that the woman is not pregnant will be determined by [1] clear indication of menopause, [2] time since last menstruation or [3] confirmation of abstinence. Women of child-bearing age will be asked to perform a pregnancy test if applicable (after obtaining their consent).
10. New catheter users.
11. Patients for whom scheduled catheter changes are more frequent than monthly.
12. Cognitive impairment affecting ability to complete outcome assessments (in the opinion of the investigator).
13. Patients who have undergone a TURP (Transurethral resection of the prostate) within the last 3 months.
14. Patients for whom a Fr14 sized dual lumen catheter would not be appropriate.

Date of first enrolment
23/02/2022

Date of final enrolment
10/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

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
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Stage 1a version 2.1	20/10/2021	18/02/2022	No	Yes
Participant information sheet	Stage 1b version 2.1	26/10/2021	18/02/2022	No	Yes
Participant information sheet	Stage 2 version 2.2	14/12/2021	18/02/2022	No	Yes
Participant information sheet	Stage 2 HCP version 2.1	26/10/2021	18/02/2022	No	Yes
Participant information sheet	Stage 2 qualitative version 2.1	26/10/2021	18/02/2022	No	Yes