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A study to test a sensor for giving early warning of urinary catheter blockage

Submission date
11/01/2023

Recruitment status
No longer recruiting

Registration date
25/01/2023

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the UK, approximately 15-25% of patients admitted to NHS hospitals each year will require urethral catheterisation. Foley catheters are often used on a long-term (≥30 days) indwelling basis, as a common management technique for urinary incontinence or retention and carry an approximate 5% per day risk of developing bacterial infections. These infections usually manifest as catheter blockages, resulting in painful distention of the bladder, and can lead to serious symptomatic episodes such as acute pyelonephritis and septicaemia.

Catheter-associated urinary tract infection (CAUTI) is the second most common cause of hospital-acquired infection, accounting for approximately 80% of hospital-acquired infections worldwide, and its prevention is an important part of patient safety initiatives in many countries. The development of CAUTI is likely to prolong a patient's hospital stay by an estimated 0.5 days to 5 days, and suffering from CAUTI adversely affects the quality of life. In the US alone, CAUTIs result in approximately $425 million in excess healthcare costs and 13,000 deaths. The aim of this study is to carry out a pilot study by recruiting around 48 catheterized patients over 5 months.

Who can participate?
Adult patients with long-term in-dwelling urinary catheters who are attending the weekly urology clinic at the Royal United Hospital in Bath

What does the study involve?
Asking volunteers to donate their used catheter drainage bags (removed in the Urology department clinic). The urine (in drainage bags) will be taken to the laboratory at the University of Bath for evaluation of urine microbiology and to test a new diagnostic lozenge that will be inserted into the urine-containing drainage bags.

What are the possible benefits and risks of participating?
The benefit of this research is that a diagnostic lozenge has been designed to give the patient, or carer, an early warning of approximately 14 hours before the onset of infection or potential

catheter blockage. The study of the donated catheter urinary bags will take place in the university laboratory, and there will be no change to the clinical pathway and thus no risks to the patient.

Where is the study run from?
University of Bath, BioPhysical research laboratory (UK)

When is the study starting and how long is it expected to run for?
October 2019 to January 2022

Who is funding the study?
Urology Foundation (UK)

Who is the main contact?
Prof Toby Jenkins (Research Chief Investigator), a.t.a.jenkins@bath.ac.uk

Contact information

Type(s)
Principal Investigator

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Prof Toby Jenkins

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261065

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44678, IRAS 261065

Study information

Scientific Title
A study to test a sensor for giving early warning of urinary catheter blockage

Acronym
URINOSTICS

Study objectives
To carry out a pilot study by recruiting around 48 catheterized patients over 5 months, and asking them to donate their used catheter drainage bags (removed in the clinic at the Urology department at the Royal United Hospital in Bath). The urine (in drainage bags) will be taken to the lab, at the University of Bath, for evaluation of urine microbiology and to test a new diagnostic lozenge (that will be inserted into the urine-containing drainage bags). The diagnostic lozenge has been designed to give the patient, or carer, an early warning (of approximately 14 hours) of the onset of infection or potential catheter blockage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/03/2020, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0) 207104828, (0)2071048272; bloomsbury.rec@hra.nhs.uk), ref: 20/LO/0094
2. Approved 18/03/2020, HRA and Health and Care Research Wales (HCRW; Castlebridge 4, Cardiff, CF11 9AB, Wales, UK; +44 (0)2920 230457; HCRW.approvals@wales.nhs.uk), ref: 20/LO /0094

Study design
Observational non-randomized unblinded single-centred 6-month study

Primary study design
Observational

Secondary study design

Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Patients requiring catheterising

Interventions
URINOSTICS lozenge - lab prototype is inserted into the urinary leg bag after patients have donated them, i.e. not part of patient pathway.

Observational:
Feasibility of study design with a view to a larger trial:
1. Practicalities of sample collection and viewing technology 'switch-on' / colour change in urine collection bags
2. pH measure of all donated urine as soon as practicable
3. A microbiological test for the presence of Proteus mirabilis in urine
4. Correlation of technology result against retrospective clinical decision of patient infection condition (time to catheter blockage following urine donation)
5. To correlate sensor switch-on with patient-reported quality of life factors
6. To undertake PPI to assess understanding of the study concept and recruitment to a study assessing the technology

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
URINOSTICS lozenge

Primary outcome measure
1. Correlation of technology result against the retrospective clinical decision of patient infection condition (time to catheter blockage following urine donation), measured using the case report form (CRF) and telephone interview at the time of donation and 3 weeks later
2. To correlate sensor switch-on with patient-reported quality of life measured using the ICIQ-Long Term Catheter quality of life (ICIQ-LTCqol) questionnaire and sensor turn-on at the time of donation, and 24 h later

Secondary outcome measures
Feasibility of study design with a view to a larger trial:
1. Practicalities of sample collection and viewing technology 'switch-on' / colour change in urine collection bags measured using visual assessment at 24 h

2. pH measure of all donated urine measured using a pH meter as soon as practicable
3. Presence of Proteus mirabilis in urine measured using standard microbiological testing of a bacterial swab taken at the time of donation. Individual bacterial species are visually identified, and freezer stocks are made. 16S rRNA sequencing was completed on the freezer stocks. The initial analysis is undertaken within 24 h and the final 16S rRNA sequencing within 6 months.

Overall study start date
07/10/2019

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Patients with long term in-dwelling urinary catheters
2. Adult aged >18 years old
3. Attendance at a weekly urology clinic
4. Consent gained for study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Total final enrolment
35

Key exclusion criteria
1. Consent not gained for study
2. Child aged < 18 years old
3. Adult without mental capacity to consent

Date of first enrolment
03/08/2021

Date of final enrolment
11/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ruh Urgent Care Centre
Combe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
University of Bath

Sponsor details
The Avenue
Claverton Down
Bath
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United Kingdom
BA2 7AY
+44 (0)1225388388
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Sponsor type
University/education

Website
http://www.bath.ac.uk/

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Research organisation

Funder Name

Urology Foundation

Alternative Name(s)
TUF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in a high impact peer-reviewed journal
2. Presentation at international conferences

Intention to publish date
01/04/2023

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 16/02/2023:
Anonymised electronic storage of the data from the trial is held securely in a DropBox folder held by the University of Bath. The preprint article of the study is available at MedRxiv.
The type of data stored: Anonymised participant data: responses from CRF, laboratory experiments, and quality-of-life questionnaire responses.
The process for requesting access (if non-publicly available): email to the corresponding author: chsataj@bath.ac.uk
Dates of availability: Anytime from the date of MedRxiv preprint publication: 26/10/2022, for the following 5 years.
Whether consent from participants was required and obtained: Informed consent was gained from participants. This data is held at Royal United Hospital, Bath. This data has been archived.
Comments on data anonymization: Researchers had no access to the identifiable data of the participants. Participants were given a study ID to allow for anonymisation. Only research nurses at the site had access to this information.
Any ethical or legal restrictions: No ethical or legal restrictions.

Previous IPD sharing statement:
The datasets generated and/or analysed during the current study are available upon request from Prof Toby Jenkins, a.t.a.jenkins@bath.ac.uk. Anonymized data from the CRF and laboratory analysis will be stored. Consent was required and obtained. Data were anonymised at the source (at the hospital), such that a list was maintained by the research nurse that correlated a unique patient ID with the patient's NHS number. This list is kept confidential by the university research team.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	05/02/2020	23/01/2023	No	Yes
Protocol file		13/05/2021	23/01/2023	No	No
Preprint results		26/10/2022	14/02/2023	No	No
HRA research summary			28/06/2023	No	No