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Antimicrobial urinary catheter safety study

Submission date
23/01/2017

Registration date
23/01/2017

Last Edited
29/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Urinary catheterisation is a procedure used to drain the bladder and collect urine, through a thin, flexible tube called a catheter. It involves the catheter being passed into the bladder via the urethra (the tube through which urine passes) so that the urine in the bladder can be drained into a collecting bag. Some patients require catheters to be in place long-term. Long-term (over 28 days) urinary catheter users are at risk of catheter-associated urinary tract infections (CAUTI). This can mean courses of antibiotics, early removal of the catheter, blockage of the catheter, and other serious complications for patients. This study will look at catheters that have been treated with three types of antimicrobial (killing microorganisms such as bacteria) drugs can prevent bacteria from attaching to the catheter to prevent infection. The aim of this study is to find out whether there are any side-effects associated with use of antimicrobial urinary catheters.

Who can participate?
Patients aged 16 years or over who have previously had a urinary catheter for at least 28 days and need another urinary catheter to be put in place for at least 28 days.

What does the study involve?
When participants are next due to have their long-term urinary catheter put in place, the antimicrobial urinary catheter is inserted (following standard procedures). Participants are then interviewed by telephone after 24, 48 and 72 hours and then weekly until the catheter is removed about their experience with the antimicrobial catheter. The catheter stays in place for the length of time needed for each individual patient. When the catheter is removed, it is sent to the lab so that bacteria levels can be tested. Participants are also interviewed at the end of the study to find out if it would be feasible to conduct a larger study.

What are the possible benefits and risks of participating?
There is no guarantee of direct benefits for those participating, however the catheters used in the study could prevent the development of CAUTI. There are no direct risks of participating other than the general risks involved with having a catheter.

Where is the study run from?
Queen's Medical Centre, Nottingham (UK)

When is the study starting and how long is it expected to run for?
June 2016 to May 2018

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

Who is the main contact?
Miss Katherine Belfield
katherine.belfield@nottingham.ac.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33365

Study information

Scientific Title
A novel antimicrobial urinary catheter for long-term catheter users: a study of its safety

Study objectives

The aim of this study is to determine whether the addition of three antimicrobials to a silicone urinary catheter produces any side effects when used in patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Edgbaston Research Ethics Committee, 12/09/2016, ref: 16/WM/0353

Study design
Non-randomised; Interventional; Design type: Prevention, Device

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Renal and Urogenital/ Other disorders of kidney and ureter

Interventions
Consenting participants will receive the antimicrobial urinary catheter at their next planned catheter insertion, and will be asked to answer questions regarding experience with the antimicrobial catheter via 15 minute telephone interviews at 24 hours, 48 hours, 72 hours and every week after the catheter is inserted.

The participants' involvement will range from 28 days to 84 days depending on their normal catheterisation schedule (i.e. if they have their catheter changed every 6 weeks, the antimicrobial catheter will remain in place for 6 weeks). The participants will also be asked to fill in a questionnaire about their interest and understanding of a future randomised controlled trial which will inform the sample size calculation and feasibility for this future study.

Finally, at the end of the trial when the catheter is removed, it will be collected and analysed in the laboratory for bacterial attachment.

Intervention Type
Device

Primary outcome measure

Rate of adverse events reported as attributable to the antimicrobial urinary catheter is measured through telephone interviews at 24 hours, 48 hours, 72 hours and every week until catheter removal.

Secondary outcome measures
1. Type of adverse events (if reported) are measured through telephone interviews at 24 hours, 48 hours, 72 hours and every week until catheter removal
2. Time to event (if reported) is measured through telephone interviews at 24 hours, 48 hours, 72 hours and every week until catheter removal
3. Removal of catheter before the end of the trial (if reported) is measured through telephone interviews at 24 hours, 48 hours, 72 hours and every week until catheter removal
4. Overall patient acceptability is measured through telephone interviews at 24 hours, 48 hours, 72 hours and every week until catheter removal
5. Catheter efficacy will be determined by collecting the trial device at the end of the trial, and examining the attached bacteria in the laboratory using standard microbiological culture techniques at study end

Overall study start date
01/06/2016

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Aged 16 years and over
2. Previously had a urethral urinary catheter for 28 days or more and will require another urethral urinary catheter for 28 days or more
3. Able to response verbally and speak on the telephone about the treatment
4. Able to understand spoken and written English and speak English fluently

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Pregnancy
2. Lacking capacity to provide consent

3. Allergy to Rifampicin, Sparfloxacin (or any other fluoroquinolone antibiotic), Triclosan or Silicone
4. History of uncontrolled/unmanageable autonomic dysreflexia
5. Significantly impaired bladder and urethral sensation

Date of first enrolment
01/12/2016

Date of final enrolment
20/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research, Enterprise, and Graduate Services
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Sponsor type
University/education

ROR

https://ror.org/01ee9ar58

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
Results will be published in a relevant journal and lay materials will be distributed to trial participants at the end of the trial.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Miss Katherine Belfield at Katherine.belfield@nottingham.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.0	26/08/2016	24/01/2017	No	Yes
Results article	results	01/01/2019		Yes	No
HRA research summary			28/06/2023	No	No