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Types of urethral catheter for reducing symptomatic urinary tract infections in hospitalised adults requiring short-term catheterisation

Submission date
22/01/2007

Recruitment status
No longer recruiting

Registration date
26/01/2007

Overall study status
Completed

Last Edited
14/07/2016

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
A urinary catheter is a flexible tube that is used to drain the bladder and collect urine. About 1 in 4 patients in hospital need a urinary catheter for a short while. This may cause a urine infection in about 7% of them, amounting to about 30,000 patients per year in the UK. These infections are important because they slow patients' recovery from illness or surgery and can lead to serious consequences such as bloodstream infections. The 15% reduction in such infections called for in the NHS Plan is hard to achieve as, unfortunately, the catheters always become contaminated with bacteria from the patient's own skin or bowel. For every day that the catheter is left in, bacteria colonise the urine in about 5% of patients. Simple measures such as general hygiene and taking the catheters out as soon as possible help to reduce the overall risk of developing a urine infection. Recently it has been shown that catheters containing antibiotics or antiseptics such as silver reduce colonisation by bacteria and may lessen the risk of infection. However, these catheters are expensive and it is not clear how much they benefit patients and whether the increased costs are matched by better health. The aim of this study is to compare the use of standard catheters with catheters containing antibiotics or antiseptics in patients who only need a catheter for a short time (less than 2 weeks).

Who can participate?
Patients aged 16 or over who need a catheter as part of their routine care

What does the study involve?
Participants are randomly allocated to have either a standard or a treated catheter. They are asked to fill in questionnaires in hospital and after they go home to find out whether a urine infection occurred and if this affected their health, treatment or hospital stay. The costs and benefits of each type of catheter are then compared to see whether one is better than another for routine use in the NHS. Sub-groups of patients who are vulnerable to severe infection, such as the elderly and those in intensive care, are also studied to see whether treated catheters might particularly benefit them.

What are the possible benefits and risks of participating?
The results of the study will allow the NHS to decide whether, for short-term use, catheters containing antibiotics or antiseptics reduce infections, result in better patient health and are cost-effective.

Where is the study run from?
University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
February 2007 to October 2010

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. James N'Dow
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Study website
https://www.charttrials.abdn.ac.uk/catheter/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 05/46/01

Study information

Scientific Title
Types of urethral catheter for reducing symptomatic urinary tract infections in hospitalised adults requiring short-term catheterisation: a randomised controlled trial

Acronym
CATHETER

Study objectives
The hypothesis being tested is that use of either of the impregnated catheters will reduce the incidence of catheter associated symptomatic urinary tract infection by 40% relative to the standard PolyTetraFluoroEthylene (PTFE) coated latex catheter (an absolute reduction of around 3%).

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/054601
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/51203/PRO-05-46-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grampian Local Research Ethics Committee (1), 07/12/2006, ref: 06/S0801/110

Study design
Three-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: https://www.charttrials.abdn.ac.uk/catheter/patientInfo.php

Health condition(s) or problem(s) studied
Urinary tract infections

Interventions
Three-arm randomised controlled trial testing three short-term urinary catheter policies in a range of high-volume clinical settings. Participants are randomised at each ward within each

centre minimised by age, sex, and whether or not participants received prophylactic or concurrent antibiotic treatment.

There are two experimental groups managed with:
1. Silver alloy impregnated hydrogel urethral catheter.
2. Nitrofurazone impregnated silicone urethral catheter.

The control group is managed with a PTFE coated latex urethral catheter - the standard control.

Intervention Type
Device

Primary outcome measure
Current primary outcome measures as of 15/05/2009:
Primary clinical outcome measure:
Incidence of symptomatic urinary tract infection at any time up to 6 weeks post randomisation (number of participants with at least one occurrence). This will be defined as any symptom reported at 3 days or 1 or 2 weeks post catheter removal or 6 weeks post-randomisation combined with a prescription of antibiotics, at any of these times, for presumed symptomatic UTI.

Subgroup analyses of the primary outcome will examine possible effect modification of age, gender, co-morbidity, duration of catheterisation, indication for catheterisation, and antibiotic use prior to enrolment.

Previous primary outcome measures:
Incidence of symptomatic urinary tract infection up to six weeks post catheter insertion (number of participants with at least one occurrence).

Secondary outcome measures
Secondary outcome measures as of 15/05/2009:

1. Secondary clinical outcome measures
1.1. Microbiological support of the primary outcome. Defined as those who fulfil the criteria for the primary outcome and in addition have any microbiologically positive result where there is >=10^4 CFU/mL of no more than two different species of uropathogen.

2. Secondary economic outcome measures
2.1. Incremental cost per infection averted and QALYs gained
2.2. Cost to the NHS and patient of the different catheters
2.3. Quality adjusted life-years (QALYs) estimated from EQ-5D responses

Tertiary outcome measures

3. Tertiary clinical outcomes
3.1. Early symptomatic urinary tract infection, defined as any self reported symptom with a prescription of antibiotics and a positive microbiological test (>=10^4 CFU/ml of no more than two different species of uropathogen) between randomisation and 3 days post catheter removal
3.2. Individually analyse the components of the definition of the primary and secondary outcome:
3.2.1. Any self-reported symptoms
3.2.2. Any antibiotic prescription for presumed symptomatic UTI.
3.2.3. Any microbiologically positive result (>=10^4 CFU/ml of no more than two different

species of uropathogen)
3.3. Health related quality of life measured by the EQ-5D up to 6 weeks
3.4. Other significant clinical events: septicaemia and mortality
3.5. Adverse effects of catheterisation apart from symptomatic UTI (e.g. urethral discomfort and pain on removal)
3.6. Antibiotic use following randomisation and indication
3.7. Assessment of the risk of antimicrobial resistance towards silver and nitrofurazone using urine specimens from patients diagnosed with symptomatic UTI and bacteriuria

Previous secondary outcome measures:

Secondary clinical outcome measures:
1. Health related quality of life measured by Short Form Health Survey (SF-36) and the EuroQoL questionnaire (EQ-5D) at six weeks
2. Other significant clinical events: septicaemia and mortality
3. Adverse effects of catheterisation apart from symptomatic Urinary Tract Infection (UTI) (e.g. urethral discomfort and pain on removal)
4. Microbial aetiology of symptomatic UTI (i.e. types of bacteria and sensitivities)
5. Incidence of asymptomatic bacteriuria
6. Antibiotic use following randomisation and indication
7. Assessment of the risk of antimicrobial resistance towards silver and nitrofurazone using urine specimens from patients diagnosed with symptomatic UTI and bacteriuria
8. Patient satisfaction with catheter (such as assessment of comfort)

Secondary economic outcome measures:
1. Incremental cost per infection averted and Quality Adjusted Life Years (QALYs) gained
2. Cost to the NHS and patient of the different catheters
3. QALYs estimated from EQ-5D responses

Overall study start date
01/02/2007

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Adult patients (both males and females, more than or equal to 16 years of age)
2. Requiring urethral catheterisation (expected to be required for a maximum of two weeks)
3. Pre-selected units with a high volume of short-term catheterisation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
5700

Key exclusion criteria
1. Patients for whom urinary catheterisation is expected to be long-term (i.e. more than 14 days)
2. Urological intervention or instrumentation within preceding seven days (e.g. catheterisation, cystoscopy, prostatic biopsy and nephrostomy insertion)
3. Non-urethral catheterisation (e.g. suprapubic catheterisation)
4. Known allergy to any of the following: latex, silver salts, hydrogel, silicone or nitrofurazone

Date of first enrolment
01/02/2007

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
United Kingdom

Study participating centre
Academic Urology Department
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University/education

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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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No
Results article	results	01/12/2012		Yes	No