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Can antibiotic prophylaxis reduce the rate of infection secondary to flexible cystoscopy and urodynamics?

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/12/2010	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RRCC045R r/2453/7000

Study information

Scientific Title

Study objectives
Flexible cystoscopy and urodynamic investigations are both commonly performed urological procedures. Published evidence suggests that around 8% of patients have an Urinary Tract Infection (UTI) at the time of these procedures and 8% will develop infection following these procedures, subsequent to UTI patients may develop septicaemia. Patients may attend their General Practitioner with a UTI and never come to the attention of the department. Whether antibiotics given at the time of urodynamics or flexible cystoscopy reduce the incidence of infection is controversial, as most studies have had inadequate sample sizes. The largest trials show reduction in infection rate when antibiotic prophylaxis is used; however these studies used intramuscular antibiotics that are expensive and uncomfortable.

The principal hypothesis addressed by this project is that oral antibiotic prophylaxis given as single dose significantly reduces the incidence of urinary tract infection following flexible cystoscopy and urodynamics. The project compares placebo with either oral ciprofloxacin or trimethoprim, in both flexible cystoscopy and urodynamics.

The project will also examine whether antibiotic prophylaxis reduces the incidence of irritative voiding symptoms following flexible cystoscopy and urodynamics. To determine the cost of antibiotic prophylaxis in flexible cystoscopy and urodynamics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Infection and infestations

Interventions
Comparison of a single dose of oral trimethoprim 200 mg or a single dose of ciprofloxacin 500 mg with placebo given to the patient one hour prior to the flexible cystoscopy or urodynamic study.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Trimethoprim and ciprofloxacin

Primary outcome(s)
1. Presence of symptomatic urinary tract infection following flexible cystoscopy or urodynamics as identified by a positive post-procedure Midstream Urine Specimen (MSU) and change in symptom score as identified using the American Urological Association (AUA) symptom bother score
2. Presence of asymptomatic bacteria following flexible cystoscopy or urodynamics as identified by a post-procedure MSU and lack of change in symptom score
3. Presence of irritative voiding symptoms following cystoscopy or urodynamics as identified by symptom score analysis in patients with a sterile MSU

A UTI will be assumed to be present if there are more than 105 cfu/ml. A urine specimen will be obtained on admission for flexible cystocopy and at the time of the procedure for urodynamics. The patients will be discharged with a sterile container to allow a mid-stream urine specimen to be performed three days after the procedure.

A simple symptom score analysis will be performed using the AUA symptom bother score questionnaire (Barry 1992). This will be filled in prior to the procedure and repeated three days after the procedure when the urine sample is returned. In addition a questionnaire detailing visits to the GP, the reason for the visit and the outcome of the visit will be completed. This questionnaire will be repeated at one month.

In order to maximise the response rate, patients failing to return their questionnaires will be followed up with a telephone call requesting completion.

Key secondary outcome(s)
Not provided at time of registration

Completion date
05/01/2002

Eligibility

Key inclusion criteria
The sample groups are drawn from adult patients who are attending the Freeman Hospital for flexible cystoscopy or urodynamics.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Patients with heart valve replacements, cardiac murmurs, orthopaedic and vascular prostheses who require definitive antibiotic prophylaxis
2. Patients on antibiotics at the time of their investigation for other reasons
3. Patients with a urethral catheter in situ at the time of the investigation
4. Patients who are allergic to either trimethoprim or ciprofloxacin
5. Patients performing intermittent clean self catheterisation

Date of first enrolment
11/01/1999

Date of final enrolment
05/01/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cancer Research UK Cambridge Research Institute
Cambridge
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Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

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	01/10/2007		Yes	No