

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

**Submission date**

23/01/2004

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

23/01/2004

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

08/12/2010

**Condition category**

Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Prevention

### Participant information sheet

**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 measure**

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 cystoscopy 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.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

11/01/1999

**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

## Age group

Adult

## Sex

Not Specified

## Target number of participants

Not provided at time of registration

## 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

England

United Kingdom

## Study participating centre

Cancer Research UK Cambridge Research Institute

Cambridge

United Kingdom

CB2 0RE

# Sponsor information

## Organisation

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

## Sponsor details

The Department of Health  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
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## Sponsor type

Government

## Website

<http://www.doh.gov.uk>

## Funder(s)

### Funder type

Government

### Funder Name

NHS Executive Northern and Yorkshire (UK)

## 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?
<a href="#">Results article</a>	results	01/10/2007		Yes	No

