# Effect of prophylactic antibiotics on post flexible cystoscopy infection rate

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
28/09/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
15/03/2016	Urological and Genital Diseases	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

# Protocol serial number

N0227189911

# Study information

### Scientific Title

Effect of prophylactic antibiotics on post flexible cystoscopy infection rate

# **Study objectives**

Are patients less susceptible to urinary tract infection post cystoscopy following administration of single-dose antibiotic prophylaxis?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Newcastle and North Tyneside 1 Ethics Committee (UK), 06/03/2007, ref: REC 07/Q0905/3

## Study design

Randomised controlled trial

### Primary study design

Interventional

# Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Urological and Genital Diseases: Urinary tract infection (UTI)

### **Interventions**

Null hypothesis: The use of a single dose oral antibiotic prophylaxis will not influence the rate of urinary tract infection post flexible cystoscopy.

Purpose: The aim of this study is to determine if patients are less susceptible to urinary tract infection post cystoscopy following administration of single-dose antibiotic prophylaxis.

Design: This study is a prospective randomised clinical trial. Every patient listed for flexible cystoscopy will be randomised appropriately, dividing them into 2 groups. One group will receive antibiotics and one group will not.

Methodology: Patients listed for flexible cystoscopy from Nov 06-March 07 will be recruited for this study. Clinicians and staff as well as the patients' GPs will be informed about this research study. Those recruited will be given a patient information sheet as well as informed consent obtained. Pre and post procedure urine samples will be obtained to objectively evaluate the presence of infection. Cystoscopies will be carried out in the surgical day unit (James Cook University Hospital) by either a specialist trainee or a consultant. External genitalia will be cleaned with topical chlorhexidine and plain lignocaine jelly 2% will be used for local anaesthetic. The cystoscope will be disinfected with Transept. 5-7 days post procedure, they would be required to return the urine samples to their respective GP. The results will be analyzed to determine the rate of positive cultures in both groups.

Predictable risks and inconvenience weighted against the anticipated benefits for participants include a small possibility of a side effect from the antibiotic. However, the antibiotic administration might prevent an infection post procedure hence the interest in this research study. The results of this study will then help develop a local protocol which will standardize the current practice. Patients may experience minor inconvenience as they have to hand in the urine sample themselves to the GP 5-7 days following the procedure.

Interpreting and analysing findings, preparing the final report will be done for around a month after the proposed recruitment date and a paper on the subject will be written and submitted to a national/international journal for peer review.

### Intervention Type

Other

### Phase

**Not Specified** 

### Primary outcome(s)

The primary outcome measure is to identify the incidence of urinary tract infection post flexible cystoscopy following prophylaxis antibiotic administration.

### Key secondary outcome(s))

No secondary outcome measures

### Completion date

30/09/2009

# **Eligibility**

### Key inclusion criteria

- 1. Male and female patients of all ages
- 2. Patients undergoing check or flexible cystoscopy

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

### Age group

**Not Specified** 

#### Sex

All

### Key exclusion criteria

- 1. High susceptibility patients who would have definitely received antibiotics diabetics, immuno compromised patients, recurrent UTIs
- 2. Patients who underwent biopsy / procedure ie stent removal etc during cystoscopy
- 3. Patients with indwelling catheters
- 4. Patients who are allergic to Penicillin

### Date of first enrolment

15/11/2006

### Date of final enrolment

# Locations

### Countries of recruitment

**United Kingdom** 

England

Study participating centre 115B Loftus House Middlesbrough United Kingdom **TS4 3TQ** 

# Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

# Funder(s)

### Funder type

Government

### **Funder Name**

South Tees Hospitals NHS Trust (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?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No