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Effect of prophylactic antibiotics on post flexible cystoscopy infection rate

Submission date	Recruitment status	[_] Prospectively registered
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

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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

30/09/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
115B Loftus House
Middlesbrough
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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