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Antibiotics with catheter withdrawal (a randomised double blind placebo controlled trial)

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/07/2009	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr H Wazait

Contact details
Department of Urology
2nd floor, Jenner Building
Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF
+44 (0)20 7288 5221

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0277104938

Study information

Scientific Title

Study objectives
Null hypothesis: antibiotic use on catheter removal does significantly reduce the risk of developing a clinically significant urinary tract infection (UTI)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urinary tract infection (UTI)

Interventions
Removing the catheter and collection of two urine samples (immediately and 7 days later). Antibiotic or placebo prescribed for 48 hours after catheter removal.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
If antibiotics are advocated, this will become a guideline for all health professionals using catheters. If antibiotics are unnecessary, this will help to decrease the incidence of antimicrobial resistance and reduce the financial burden of antibiotic use in this group.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/10/2001

Completion date
01/10/2004

Eligibility

Key inclusion criteria
150 in-patients with in-dwelling catheters about to be removed will be blinded into two arms of the study (test and placebo)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/10/2001

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Urology
London
United Kingdom
N19 5NF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Whittington Hospital NHS Trust (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?
Results article	results	01/11/2004		Yes	No