

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

Submission date
30/09/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/09/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
09/07/2009

Condition category
Urological and Genital Diseases

☐ Individual participant data

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