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Bacteraemia post-urological instrumentation: endocarditis risk?

Submission date	Recruitment status	[_] Prospectively registered
12/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/12/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/07/2016	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A one-year, prospective, observational, cohort, single centre study on the incidence, intensity, duration and identity of bacteraemia in patients undergoing transurethral resection of the prostate (TURP), extracorporeal shockwave lithotripsy (ESWL) and urinary catheter change

Study objectives
Primary hypothesis:
Instrumentation during urological procedures does not cause bacteraemia.

Secondary hypothesis:
There is no link between infective endocarditis and preceding surgical instrumentation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds Central Research Ethics Committee approval pending as of 13/10/2009

Study design
Prospective observational cohort single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The enrolled participants will provide a urine sample prior to the start of their procedure. They will then have an intravenous cannula inserted aseptically, preferably in their antecubital fossa. The cannula will be connected to a 3-way tap, with one output connected to a slow-drip to keep the cannula patent. The other output will be used to acquire blood for the study.

20 ml of blood will be withdrawn from the cannula at the following time-points:
1. 5 minutes pre-procedure

2. 2 minutes into the procedure
3. 5 minutes into the procedure
4. 10 minutes into the procedure
5. End of the procedure
6. 10 minutes after the end of the procedure
7. 30 minutes after the end of the procedure
8. 60 minutes after the end of the procedure

The blood thus acquired will be transferred into commercially available aerobic and anaerobic blood bottles. These samples will be processed in the laboratory by the chief investigator within a reasonable time frame (within 3 hours) and used for culture and polymerase chain reaction (PCR) methods to identify the bacteria both qualitatively and quantitatively.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Presence of bacteraemia, assessed at time of culture and PCR

Secondary outcome measures
Development of infective endocarditis. A year after obtaining the samples, participants will be contacted by phone or mail to see whether they have suffered an episode of infection in that year which required hospital admission. If that is the case, the hospital notes of the said patients will be obtained and data collected from the notes about the said episode of infection.

Overall study start date
01/12/2009

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Adults (18 years onwards)
2. Both male and female (male only for the transurethral resection of the prostate [TURP] cohort)
3. Patient undergoing TURP, extracorporeal shock-wave lithotripsy and urinary catheter change at the Leeds Teaching Hospital NHS Trust

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
TURP: 200; ESWL: 250; Catheter-Change: 300

Key exclusion criteria
1. Age less than 18 years
2. Not competent to consent for enrolment in the study
3. Signs and symptoms of ongoing infection (of any source) at presentation to the hospital
4. Use of systemic antibiotics within the 2 weeks of presentation to the hospital
5. Recent (within 2 weeks) instrumentation of the urological tract (not including urethral or suprapubic catheterisation)
6. Patient with poor veins, leading to difficult venous cannulation

Date of first enrolment
01/12/2009

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Urology Department
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
Beckett St
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+44 (0)113 243 3144
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Sponsor type
Hospital/treatment centre

Website
http://www.leedsteachinghospitals.com/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals 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