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Treatment with ciprofloxacin for one or two weeks in women with acute pyelonephritis.

Submission date	Recruitment status	[_] Prospectively registered
07/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/08/2012	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-004992-39

Protocol serial number
2005-004992-39

Study information

Scientific Title

Acronym
STRAMA/Py2005

Study objectives
The null hypothesis to be tested: the difference in the proportion of patients with clinical failure or symptomatic recurrence ten to 14 days after completed treatment is larger than 10% when seven and 14 days of treatment are compared.

Pleaes note that the anticipated end date of this trail has been updated from 31/01/2008 to 31 /12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Research Ethics Committee at Götebrog University 23/12/2005.

Study design
A randomised, double blind, placebo-controlled multi centre study with parallel groups.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute pyelonephritis in women

Interventions
All patients are treated with ciprofloxacin 500 mg twice daily orally for seven days. Half of the study group will continue treatment with ciprofloxacin 500 mg twice daily for another seven days while the other half will be treated with placebo during the same period.

Added as of 24/10/2008: The anticipated end date of recruitment is 31/12/2008. The last follow-up visit will be approximately two months (42-63 days) after inclusion of the participant into the trial.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Clinical and bacteriological efficacy of seven and 14 days treatment with ciprofloxacin 500 mg twice daily in women with acute pyelonephritis. Outcome will be measured ten to 14 days after ciprofloxacin treatment has been discontinued.

Key secondary outcome(s))
The accumulated clinical and bacteriological efficacy will be assessed five to seven weeks after ciprofloxacin treatment is discontinued.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Women 18 years of age or older with suspected acute pyelonephritis
2. Fever of 38 degrees Celsius or more
3. Flank pain and/or costo-vertebral angle tenderness and/or voiding difficulties
4. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Pregnancy
2. Breast-feeding
3. Women of a fertile age who are not using adequate contraceptives
4. Known hypersensitivity to fluoroquinolones
5. Antibiotic treatment within the last 72 hours
6. Patient with permanent indwelling urinary catheter or intermittent catheterization of the urinary bladder
7. Patient previously included in this study
8. Patient with known renal insufficiency (creatinine clearance <30 ml/min)
9. Patient with epilepsy
10. Patient treated with antacids, sucralfate, zinc or theophylline
11. Other reason according to the investigator´s discretion

Date of first enrolment
23/02/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Infectious Diseases
Göteborg
Sweden
S-416 85

Sponsor information

Organisation
Swedish Institute for Infectious Disease Control, Strama (Sweden)

ROR
https://ror.org/05x4m5564

Funder(s)

Funder type
Research organisation

Funder Name
Swedish Institute for Infectious Disease Control, Strama (Sweden), Swedish Strategic Programme for the Rational Use of Antimicrobial Agents

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?
Results article	results	04/08/2012		Yes	No