

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

Submission date 07/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/08/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

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
2005-004992-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Please note that the anticipated end date of this trial 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 Göteborg University 23/12/2005.

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

The accumulated clinical and bacteriological efficacy will be assessed five to seven weeks after ciprofloxacin treatment is discontinued.

Overall study start date

23/02/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

260 patients

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)

Sponsor details

Swedish Strategic Programme for the Rational Use of Antimicrobial Agents

Swedish Institute for Infectious Disease Control

Solna

Sweden

S-171 82

Sponsor type

Research organisation

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

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	04/08/2012		Yes	No