Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of single dose and three-day course of Cefixime in women with acute cystitis

Protocol summary

Summary

1-Objectives: The aim of this study was to compare the efficacy of single dose and three days course of Cefixime in women with uncomplicated acute cystitis. 2-Design: The method of this study is 2to3 phases of clinical trial. 3- Setting and conduct: The subjects were referred to urologic and gynecologic clinic at Bou Ali Hospital in Tehran (Iran)due tourinary tract diseases symptoms. 4- Participants including major eligibility criteria:70 eligible women referring to following criteria had been selected: Inclusion criteria : fertility age(50-15 age); fully functional immunity system Exclusion criteria : menopause; pregnancy; abnormality of Urinary Tract; history of Urinary Tract surgery& Sondage ; systemic symptoms (e.g,fever, lumbar pain); use of Intra Uterine Device; sensitivity to Penicillins&Cephalosperins; history of Diabetis Mellitus 5- Intervention: subjects had been randomly divided in two groups (35 persons). The first group (Intervention group) was prescribed one 800 mg dose of Cefixime and the 2nd group (Control group) was treated with 400mg/day Cefixime for 3 days. 6- Main outcome variables: The main outcome which has been assessed was the positiveness of urine culture test after one and two weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204189505N1**
Registration date: **2013-01-01, 1391/10/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-01, 1391/10/12

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Islamic Azad University Tehran Medical Branch

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2008-03-19, 1386/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of single dose and three-day course of Cefixime in women with acute cystitis

Public title

Comparison of single dose and three-day course of Cefixime in women with acute cystitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : fertility age(50-15 age); fully functional immunity system Exclusion criteria : menopause; pregnancy; abnormality of Urinary Tract;

history of Urinary Tract surgery& Sondage ; systemic symptoms (e.g,fever, lumbar pain); use of Intra Uterine Device; sensitivity to Penicillins&Cephalosperins; history of Diabetis Mellitus

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Vice chancellor for research,Islamic Azad University Tehran Medical Branch

Street address
Tehran Medical Branch , Islamic Azad University, khaghani st, shariati Ave , Tehran, Iran

City
Tehran

Postal code
19168

Approval date
2007-04-21, 1386/02/01

Ethics committee reference number
2628

Health conditions studied

1

Description of health condition studied
Acute Cystitis

ICD-10 code
N30.0

ICD-10 code description
Acute Cystitis

Primary outcomes

1

Description
positiveness of urine culture test

Timepoint
after one and two weeks from finishing the prescribed antibiotics.

Method of measurement
Urine Culture test

Secondary outcomes

empty

Intervention groups

1

Description
The first group (Intervention group) was prescribed one dose/ 800 mg of Cefixime .

Category
Treatment - Drugs

2

Description
The 2nd group (Control group) was treated with 400mg/day Cefixime for 3 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Urologic and Gynecologic clinic at Boo Ali Hospital in Tehran (Iran)

Full name of responsible person
Fatemeh Mohammadyari

Street address
Damavand St., Imam Hossein Sq., Tehran-Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Islamic Azad University Tehran Medical Branch

Full name of responsible person
Mr Naghipour

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Tehran Medical Branch , Islamic Azad UniversityT, khaghani st, shariati Ave , Tehran, Iran

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Islamic Azad University Tehran Medical Branch
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty