

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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 to urinary 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 Diabetes 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

Name

Fatemeh Mohammadyari

Name of organization / entity

Islamic Azad university Tehran Medical Branch

Country

Iran (Islamic Republic of)

Phone

+98 220066607009821

Email address

fmohammadyari@iautmu.ac.ir

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

Street address

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

Contact

Name of organization / entity
Islamic Azad university Tehran Medical Branch

Full name of responsible person
Dr Fatemeh Mohammadyari

Position
Gynecologist-Assistant professor of Islamic Azad
university Tehran Medical Branch

Other areas of specialty/work

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

City
Tehran

Postal code

Phone
+98 21 3334 8036

Fax

Email
fmohammadyari@iautmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad university Tehran Medical Branch

Full name of responsible person
Dr Fatemeh Mohammadyari

Position
Gynecologist-Assistant professor of Islamic Azad

university Tehran Medical Branch

Other areas of specialty/work

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

City
Tehran

Postal code

Phone
+98 21 3334 8036

Fax

Email
fmohammadyari@iautmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University Tehran Medical Branch

Full name of responsible person
Dr Fatemeh Mousavi

Position
Community Medicine Specialist, Associate professor
of Islamic Azad University Tehran Medical Branch

Other areas of specialty/work

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

City
Tehran

Postal code
19395

Phone
+98 21220066607

Fax
ati35983@yahoo.com

Email
ati35983@yahoo.com

Web page address

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