

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparative study on the effect of treatment of dietary regimens of Cotrimoxazole - Ciprofloxacin- Cefixime in the treatment of uncomplicated cystitis in females over 18 years of age

Protocol summary

Study aim

Determining the effect of cotrimoxazole, ciprofloxacin, cefixime in the treatment of uncomplicated cystitis in women over 18 years of age

Design

Clinical trial without control group, with parallel groups, without blinding, non-random, phase 2-3 on 150 patients

Settings and conduct

In this study, 150 women over the age of 18 with uncomplicated cystitis who Will refer to private health centers in Shahroud in 1399 are studied. Fifty people were treated with cotrimoxazole (400/160 twice a day) and Fifty people were treated with ciprofloxacin (500 mg twice daily) and Fifty people were treated with (400 mg once daily).At the same time as filling file and questionnaire, the first stage tests (U / A-U / C) are requested for the patient. and questionnaire , first stage tests (U/A - U/C) are requested for the patient. In the second visit (7-10 days later), the second stage tests are also requested. In the third stage, a month later, the patients who had a positive treatment response are evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Women over 18 with uncomplicated cystitis in Shahroud Exclusion criteria: Patients who cannot be accessed for any reason , have underlying and concomitant illnesses, take certain medications, people with anatomical disorders of the urinary tract, pregnant, lactating women

Intervention groups

1) First intervention group: 50 people treated with cotrimoxazole 400/160 twice a day 2) Second intervention group: 50 people treated with ciprofloxacin 500 mg, twice a day 3)Third Intervention group: 50 people treated with cefixime 400 mg , once a day

Main outcome variables

Symptoms of cystitis : Dysuria , Frequency ,Suprapubic

pain, Polyuria,Urgency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200414047073N1**

Registration date: **2020-10-17, 1399/07/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-17, 1399/07/26**

Update count: **0**

Registration date

2020-10-17, 1399/07/26

Registrant information

Name

Reihane Pishrouyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3377 1895

Email address

r.pishrouyan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the effect of treatment of dietary regimens of Cotrimoxazole - Ciprofloxacin- Cefixime in the treatment of uncomplicated cystitis in females over 18 years of age

Public title

Comparative study on the effect of treatment of dietary regimens of Cotrimoxazole - Ciprofloxacin - Cefixime in the treatment of uncomplicated cystitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women over 18 years old with uncomplicated cystitis living in Shahroud

Exclusion criteria:

Patients who cannot be accessed for any reason Patients with a history of underlying chronic disease Taking anticoagulants or continuous contraceptives People with anatomical disorders of the urinary tract Taking oral or injectable antibiotics prophylactically in the last 2 weeks Pregnant women lactating women Taking contraceptives Patients with concomitant diseases Patients with a positive history of kidney disease Diabetic patients history of seizure Patients with systemic infection Patients with flank pain Patients with signs of urinary tract infection more than 72 hours Resistance to all three drugs

Age

From 18 years old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Not 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**

Ethics committee of shahroud Islamic Azad University
Of medical Sciences

Street address

Shahroud Islamic Azad Univesity ,University
Blvd,shahroud ,Semnan

City

shahroud

Province

Semnan

Postal code

43189-36199

Approval date

2019-07-08, 1398/04/17

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1398.037

Health conditions studied**1****Description of health condition studied**

سیستیت بدون عارضه

ICD-10 code

N30

ICD-10 code description

Cystitis

Primary outcomes**1****Description**

Urinary tract infection status

Timepoint

First visit, second visit (7 to 10 days later), third visit
(one month later)

Method of measurement

U/A- U/C

2**Description**

Symptoms of cystitis(Dysuria,Frequency ,Suprapubic
Tenderness,polyuria,Urgency)

Timepoint

First visit, second visit (7 to 10 days later), third visit
(one month later)

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: 50 people treated with cotrimoxazole 400/160 twice a day

Category

Treatment - Drugs

2

Description

Second intervention group: 50 people treated with ciprofloxacin 500 mg twice daily

Category

Treatment - Drugs

3

Description

Third intervention group: 50 people treated with cefixime 400 mg once daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Beyki 's Private Office

Full name of responsible person

Reihane Pishrouyan

Street address

Unit 14, 3rd Floor,Bahar Doctors Building, 22 Bahman St., Shahroud

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2

Recruitment center

Name of recruitment center

Dr. Monire Amerian Private Office

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Reihane pishrouyan

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Public Health

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A Level or less
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available