Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Tendernes،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
Reihane Pishrouyan
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r.pishrouyan@gmail.com
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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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