Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the therapeutic effect of ciprofloxacin and Combination of ciprofloxacin and propolis on women with cystitis

Protocol summary

Study aim
Comparison of ciprofloxacin and compound of ciprofloxacin and propolis therapy on women with sistit

Design
The present study is a seven-day intervention with propolis or placebo extract in women with cystitis. Written consent will be obtained from the patients participating in the study at the time of registration. Eligibility will be evaluated for the inclusion criteria first. The patients were allocated to either an intervention or placebo group by block randomization. The sample size will be 60 for each group. Qualified participants are randomly assigned to one of two groups. Participants will be blind in the study. Before and after the intervention. clinical symptoms and laboratory tests will be measured.

Settings and conduct
Qom University of Medical Sciences, Kamkaran Arab Nia Hospital

Participants/Inclusion and exclusion criteria
Women with UTI; lower urinary tract infection for the first time; no chronic disease

Intervention groups
Intervention group: Propolis extract at a dose of 500 mg twice daily for seven consecutive days and 250 mg ciprofloxacin twice daily Control group: placebo at a dose of 500 mg twice daily for seven consecutive days and 250 mg ciprofloxacin twice daily

Main outcome variables
Bacteria count, Red blood cell in urine, clinical symptoms including hematuria, urinary frequency, dysuria, suprapubic pain, and urgency, ESR, CRP

General information

Reason for update
اصلاح بعضی قسمت های مطالعه (تعداد کل شرکت کنندگان مطالعه و روش تصادفی سازی) که در نسخه ی اول اشتباه تایپ شده بود

Acronym

IRCT registration information
IRCT registration number: **IRCT20180721040552N1**
Registration date: **2019-04-04, 1398/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**
Update count: **1**

Registration date
2019-04-04, 1398/01/15

Registrant information

Name
Mehdi Shekari
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-17, 1397/12/26

Expected recruitment end date
2019-05-16, 1398/02/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the therapeutic effect of ciprofloxacin and Combination of ciprofloxacin and propolis on women with cystitis

Public title

Comparison of the therapeutic effect of ciprofloxacin and Combination of ciprofloxacin and propolis on women with cystitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with UTI (cystitis) Age between 18 and 60 years lower urinary tract infection for the first time

Exclusion criteria:
Alcohol use Chronic disease Taking antibiotics and other drugs

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were allocated to either an intervention or placebo group by block randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
Propolis capsules and placebo capsules were completely identical in packages and were coded by the researcher so that the studied subjects did not know the type of package contents.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qom University of Medical Sciences

Street address
Shahid Lavasani ave

City
Qom

Province
Ghoum

Postal code
3713649373

Approval date
2019-03-04, 1397/12/13

Ethics committee reference number
ir.muq.rec.1397.200

Health conditions studied

1

Description of health condition studied
Cystitis

ICD-10 code
N30.8

ICD-10 code description
Other cystitis

Primary outcomes

1

Description
Urinary bacteria

Timepoint
At the beginning of the study and 7 days after the start of the study

Method of measurement
Urine culture

Secondary outcomes

1

Description
White blood cells

Timepoint
At the beginning of the study and 7 days after the start of the study

Method of measurement
Blood test

2

Description
Clinical symptoms

Timepoint
At the beginning of the study and 7 days after the start of the study

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Every 12 hours, a supplement of 500 mg propolis and one 250 mg ciprofloxacin control

Category
Treatment - Other

2

Description
Control group: Placebo and ciprofloxacin 250 mg every 12 hours
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamkaran Arab Nia hospital
Full name of responsible person
Dr Mohammad Heydari
Street address
19Dey Ave
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Sponsors / Funding sources

1

Sponsor
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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
Ghoum University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ghoum University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information on the main outcome of the study

When the data will become available and for how long
After printing the article

To whom data/document is available
All people

Under which criteria data/document could be used
To conduct scientific studies

From where data/document is obtainable
Personal email

What processes are involved for a request to access data/document
Send mail

Comments