

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3883 6354

Email address

mehdishekari025@gmail.com

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

2019-03-04, 1397/12/13

Ethics committee reference number
ir.muq.rec.1397.200

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

Ghous

Postal code

3713649373

Approval date

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

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19Dey Ave

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Sponsors / Funding sources

1

Sponsor

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Ghous University of Medical Sciences

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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Mehdi Shekari

Position

Master of Science In Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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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