

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the oral formulation of pomegranate peel extract efficacy for the treatment of cystitis

Protocol summary

Study aim

Evaluating the effectiveness of oral extract of pomegranate peel in accelerating the improvement of symptoms in patients with cystitis

Design

Clinical trial with a control group, triple-blind design, phase three, is conducted on 40 patients, and randomization is performed using the randomization site for the purpose of randomization.

Settings and conduct

In this study, 40 patients with cystitis at Dr.Tavanaee 's clinic receive 250 milligrams of pomegranate peel extract thrice daily for seven days. A control group is also included, with randomization conducted using randomization software. The study is triple-blinded, with the patient, data analyst, and researcher all being blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Women aged between 18-65 years
2. Suffering from acute uncomplicated cystitis based on clinical symptoms and U/A
3. Signing a written informed consent
Non-inclusion criteria: 1. Simultaneous use of phenazopyridine
2. Taking cranberry and probiotic supplements
3. History of allergy to pomegranate and its derivatives
4. Taking warfarin or cyclosporine and tacrolimus
5. History of severe constipation or hemorrhoids

Intervention groups

The intervention group will receive a capsule containing 250 mg of pomegranate peel extract three times a day for one week, and the control group will receive a placebo capsule containing lactose three times a day with the exact instructions as the drug group.

Main outcome variables

Primary Outcome: Assessing the severity of the Symptom Score ACSS questionnaire at the study's outset and on the third, fifth, and seventh days if symptoms persist. Secondary Outcome: Examining potential side effects by the physician and pharmacy student evaluator

during visits. Comparing dysuria resolution day and urination frequency between the two comparison groups based on patient self-reports.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N15**

Registration date: **2024-01-03, 1402/10/13**

Registration timing: **prospective**

Last update: **2024-01-03, 1402/10/13**

Update count: **0**

Registration date

2024-01-03, 1402/10/13

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1588

Email address

elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the oral formulation of pomegranate peel extract efficacy for the treatment of cystitis

Public title
Evaluation of pomegranate peel extract in bladder infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Acute cystitis based on clinical symptoms Signing a written informed consent
Exclusion criteria:
Simultaneous use of phenazopyridine Taking cranberry and probiotic supplements History of allergy to pomegranate and its derivatives Taking warfarin or cyclosporine and tacrolimus History of severe constipation or hemorrhoids

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will use the block randomization method to generate a sequence of random numbers. In this method, eight blocks of size 4 and 4 blocks of size two are randomly selected from the combination of letters A and B with a table of random numbers. The list of blocks of size two is 1:AB, 2:BA, and the list of blocks of size four is: 1:AABB, 2:ABBA, 3:BBAA, 4:BAAB, 5:BABA, 6:ABAB. To select blocks of size 2, 4 numbers are randomly selected from the table of random numbers. If this number is from 0 to 4, the first block is selected, and if the number is from 5 to 9, the second block is selected. To select blocks of size 4, 8 numbers between 1 and 6 are randomly selected from the table of random numbers. Then, if this number is 1, the first block of size 4, and if the chosen number is 2, the second block and so on are selected.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the method of triple blinding includes the participants themselves, the outcome assessor (including the pharmacist), and the clinical supervisor (specialist doctor). The people mentioned in this study do not know

about the type of medicine, either placebo or medicinal substance. The person who prepares the study's draft (pharmacist) needs to learn the nature of the substance used.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mashhad University of Medical Sciences

Street address

Kalantari entry, School of Pharmacy,Mashhad University of Medical Sciences, Vakil-Abad Blvd, Mashhad town

City

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9177948954

Approval date

2023-08-19, 1402/05/28

Ethics committee reference number

IR.MUMS.REC.1402.146

Health conditions studied

1

Description of health condition studied

Cystitis

ICD-10 code

N30.9

ICD-10 code description

Cystitis, unspecified

Primary outcomes

1

Description

Score of improvement of disease symptoms

Timepoint

At the beginning of the study and then at the end of the third, fifth day and if the symptoms remain, on the seventh day.

Method of measurement

Acute cystitis symptom scoring criteria evaluation questionnaire (ACSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive capsules containing 250 mg of pomegranate peel extract three times a day for one week.

Category

Rehabilitation

2

Description

Control group: The control group will receive placebo capsules containing lactose three times a day for one week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal office of Dr Zahra Tavanaei

Full name of responsible person

Sepideh Elyasi

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Imam Reza Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

The findings will be published in an article. Study protocol and statistical analysis will be used for article publication.

When the data will become available and for how long

One year after the end of the study it will be published and available in databases.

To whom data/document is available

The findings will be available for researchers, clinicians, and scientific centers if the funding sponsor allows.

Under which criteria data/document could be used

The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable

For this purpose, you can contact with Sepideh Elyasi, at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

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

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks.

Comments