

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation the effect of topical use of chamomile oil on appeasing of patients with interstitial cystitis: A triple randomized placebo-controlled trial

Protocol summary

Study aim

The aim of this study was to evaluate the local effect of chamomile oil on the severity of symptoms in patients with interstitial cystitis.

Design

Randomised controlled clinical trial and triple blind, parallel study

Settings and conduct

This study is conducted at Kamkar Hospital in Qom and is blinded by placebo

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients elder than 18 years old and history of more than nine months of bladder inflammation. Patients with concomitant symptoms of genital pain, frequent urination and bladder burning. Exclusion criteria: Suffering from intestinal diseases such as Crohn's disease, colitis, peptic ulcer, irritable bowel syndrome (IBS) History of myocardial infarction; coronary bypass surgery during last 6 month Pregnant women or women who want to have a pregnancy

Intervention groups

patient with Interstitial cystitis symptoms which is divided into two groups of chamomile oil and placebo oil. placebo oil similar to the drug.

Main outcome variables

Interstitial cystitis symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170112031893N2**

Registration date: **2018-11-13, 1397/08/22**

Registration timing: **prospective**

Last update: **2018-11-13, 1397/08/22**

Update count: **0**

Registration date

2018-11-13, 1397/08/22

Registrant information

Name

Hossein Yusefi

Name of organization / entity

Qom University of medical science

Country

Iran (Islamic Republic of)

Phone

+98 25 3886 0146

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driran1399@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of topical use of chamomile oil on appeasing of patients with interstitial cystitis: A triple randomized placebo-controlled trial

Public title

Evaluation the effect of topical use of chamomile oil on appeasing of patients with interstitial cystitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients elder than 18 years old and history of more than nine months of bladder inflammation Patients with concomitant symptoms of genital pain, frequent urination and bladder burning

Exclusion criteria:

Suffering from intestinal diseases such as Crohn's disease, colitis, peptic ulcer, irritable bowel syndrome (IBS) Pregnant women or women who want to have a pregnancy History of myocardial infarction; coronary bypass surgery during last 6 month

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by Throwing coin and dice

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients, statistical analyst and physicians are not aware of the allocation of drugs and placebo, and someone outside the group is aware of the allocation of treatment. The placebo is a yellow-colored oil that is similar in color to chamomile oil.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research of Qom
University of Medical Sciences

Street address

Plaque 83, 4th Alley, 1/1 Lane, Safashar Street

City

Qom

Province

Ghous

Postal code

87366-37169

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.MUQ.REC.1397.088

Health conditions studied

1

Description of health condition studied

Interstitial cystitis

ICD-10 code

N30.1

ICD-10 code description

Interstitial cystitis (chronic)

Primary outcomes

1

Description

Symptom of Interstitial Cystitis

Timepoint

Prior to study, second week, fourth week , eighth week
and at the end of study

Method of measurement

O leary index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group used chamomile oil
amount 5 cc for 2 months, every day in the bladder area

Category

Treatment - Drugs

2

Description

Control group: The group used placebo oil amount 5 cc
for 2 months, every day in the bladder area

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamkar & Arab nia hospital

Full name of responsible person

Muhammad kazem Moslemi

Street address

Kamkar-Arabnia hospital, 19 Day street, Qom, Iran

City

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3713649373

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Email

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Position

Professor assistant

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Qom University of medical science

Full name of responsible person

Hossein Saghafi

Street address

2nd floor, No. 83, lane 4, alleys 1/1, Safashahr street,
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driran1399@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The Qom University of medical science

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

Ghousm University of Medical Sciences

Full name of responsible person

Fatemeh Nojavan

Person responsible for scientific inquiries

Contact

Name of organization / entity

The Qom University of medical science

Full name of responsible person

Muhammad hossein Yusefi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Service Management

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Person responsible for updating data

Contact

Name of organization / entity

The Qom University of medical science

Full name of responsible person

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Position

student

Latest degree

Bachelor

Other areas of specialty/work

Internal medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

With attention due to the type of study and publication of the article, there was no need to mention this

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available