Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 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

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Hossein Yusefi

Name of organization / entity
Qom University of medical science

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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

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Province

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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
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Kamkar-Arabnia hospital, 19 Day street, Qom, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Qom University of medical science
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2nd floor, No. 83, lane 4, alleys 1/1, Safashahr street, Qom, Iran
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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
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
Ghoum University of Medical Sciences
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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