

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the effectiveness of Cinnamon Oil Soft Capsule on Bloating in patients with Functional Dyspepsia

#### Protocol summary

##### Study aim

The goal of this randomized double blind placebo controlled clinical trial is to prescribe Cinnamon oil soft capsule for functional dyspepsia patients and evaluation of the efficacy of this natural remedy.

##### Design

In this research, 68 patients will be treated randomly with either Cinnamon oil soft capsule (intervention) or placebo (control) three times a day for 6 weeks. Each time, 1 capsule is used.

##### Settings and conduct

This study is done in Imam Reza hospital of Kermanshah University of Medical Sciences. Blinding is done for patients and physician who measure the outcome of the study. Randomization is performed using blocking method.

##### Participants/Inclusion and exclusion criteria

Major inclusion criteria include: 18<age<80; patients who sign the testimonials and cooperate during the study and patients who have not been treated with Cinnamon oil soft capsule during the last month, and main exclusion criteria include: Patients with peptic ulcer disease, inflammatory bowel disease, irritable bowel syndrome, pure gastro-esophageal reflux disease; Patients with a history of gastrointestinal system surgery and pregnant and breast-feeding women.

##### Intervention groups

Intervention: oral use of Cinnamon oil soft capsule three times a day for 6 weeks. Control: oral use of Sesame oil soft capsule three times a day for 6 weeks.

##### Main outcome variables

Bloating

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170802035460N2**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

##### Registration date

2017-12-29, 1396/10/08

##### Registrant information

###### Name

Fateme Parvizi

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3429 9220

###### Email address

fatemeparvizi4@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-22, 1396/10/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of Cinnamon Oil Soft Capsule on Bloating in patients with Functional Dyspepsia

##### Public title

Effect of Cinnamon Oil Soft Capsule on Functional Dyspepsia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 18 and 80 Patients who sign the testimonials and cooperate during the study Patients who have not been treated with Cinnamon Oil Soft Capsule during the last month Patients who their diseases are confirmed by complete medical evaluation including colonoscopy, pathology and laboratory data

### Exclusion criteria:

Patients with peptic ulcer disease, inflammatory bowel disease, irritable bowel syndrome, pure gastro-esophageal reflux disease Biliary motility disorder and any organic gastrointestinal disease Patients with a history of gastrointestinal system surgery Patients with background systemic diseases such as diabetes mellitus, heart failure, hepatic failure, renal failure, asthma, chronic obstructive pulmonary disease Patients with severe psychiatric diseases Patients addicted to alcohol and opium pregnant and breast-feeding women Taking any routine medication such as cardiac, antihypertensive, antipsychotic, antianxiety, corticosteroids drugs, Iron or calcium supplements and antibiotics

## Age

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

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **68**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is performed using blocking method.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Blinding is done for patients and physician who measure the outcome of the study.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Kermanshah University of Medical Sciences, Faculty of pharmacy, Daneshgah Ave., Shahid Shiroodi Blvd.

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Approval date

2017-11-25, 1396/09/04

##### Ethics committee reference number

KUMS.REC.1396.448

## Health conditions studied

### 1

#### Description of health condition studied

functional dyspepsia

#### ICD-10 code

K30

#### ICD-10 code description

Functional dyspepsia

## Primary outcomes

### 1

#### Description

Bloating

#### Timepoint

At the beginning of the study, 2, 4 and 8 weeks after starting the soft capsule of cinnamon oil

#### Method of measurement

Gastrointestinal Symptom score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: use a soft capsule of cinnamon oil three times a day for 6 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: oral use of Sesame oil soft capsule three times a day for 6 weeks.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Dr. Mohammad Hosein Farzaei

**Street address**

Imam Reza Hospital, Parastar Blvd., Kermanshah

**City**

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6714415333

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mh-farzaee@razi.tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mohamad Hosein Farzaei

**Street address**

Kermanshah University of Medical Sciences, Faculty of pharmacy, Daneshgah Ave., Shahid Shiroodi Blv., Kermanshah

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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**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Fateme Parvizi

**Position**

Investigator

**Latest degree**

Master

**Other areas of specialty/work**

Others

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Hosein Farzaei

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Fateme Parvizi

**Position**

Investigator

**Latest degree**

Master

**Other areas of specialty/work**

Others

**Street address**

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Daneshgah St., Sorkheligeh, Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714694451

**Phone**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available