

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

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Position

Assistant Professor

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Specialist

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Medical Pharmacy

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Person responsible for updating data

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Full name of responsible person

Fateme Parvizi

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Latest degree

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Other areas of specialty/work

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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