

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluating the effects of standardized hydroalcoholic extract of marmotti (Salvia mirzayanii Rech. f. & Esfand) capsule as adjunctive treatment in patient with helicobacter pylori infection

Protocol summary

Study aim

Evaluating the effects of capsules containing standardized hydroalcoholic extract of marmotti (Salvia mirzayanii Rech. F. & Esfand) as adjunctive therapy in patients with Helicobacter pylori infection

Design

This study is a randomized, double-blind, controlled clinical trial with a parallel group design of 50 patients.

Settings and conduct

Patients are selected from Kerman Baysat Clinic. Participants and physicians are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with dyspepsia and gastrointestinal symptoms, and with Helicobacter pylori infection is diagnosed with stool antigen test. Exclusion criteria: Previous treatment for Helicobacter pylori eradication; penicillin or bitter merov plant allergy and gastric cancer.

Intervention groups

The treatment group received two 500 mg capsules containing bitter extract twice daily and the control group received the same placebo in terms of shape, color, and packaging with the same dose of the treatment group.

Main outcome variables

Stool antigen test is performed at baseline and 4 weeks after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110310006026N9**

Registration date: **2019-09-23, 1398/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-23, 1398/07/01**

Update count: **0**

Registration date

2019-09-23, 1398/07/01

Registrant information

Name

Fatemeh Dabaghzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of standardized hydroalcoholic extract of marmotti (Salvia mirzayanii Rech. f. & Esfand) capsule as adjunctive treatment in patient with helicobacter pylori infection

Public title

Evaluating the effects of standardized hydroalcoholic extract of marmotti (Salvia mirzayanii Rech. f. & Esfand)

capsule as adjunctive treatment in patient with helicobacter pylori infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient with dyspepsia and gastrointestinal symptoms with Helicobacter pylori infection who diagnosed with stool antigen test
Exclusion criteria:
 Earlier treatment of Helicobacter pylori eradication
 Allergic to penicillin or marmotti Stomach cancer

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The eligible participants are allocated to one of the two study groups in a 1:1 ratio. Allocation is by block randomization with a block size of four. A person (not involved in the trial) generates allocation sequence

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and physician: marmotti and placebo capsules had the same shape, color and outer packaging.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Beginning of Jahad Blvd., Tahmasebad Fourways

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Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-08-25, 1398/06/03

Ethics committee reference number

IR.KMU.REC.1398.251

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Stool antigen

Timepoint

The first and second weeks after the beginning of the study and 4 weeks after the end of the study

Method of measurement

Stool antigen test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The treatment group receive 2 capsules of 500 mg containing bitter mulberry extract twice daily for 14 days.

Category

Treatment - Drugs

2

Description

Control group: They receive two 500 mg capsules of placebo twice daily for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Besaat Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Kerman 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
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Fatemeh Dabaghzadeh
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Assistant professor
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Person responsible for updating data

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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

There is no further information

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

Undecided - It is not yet known if there will be 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