

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of the poly-herbal preparation, “Ghors-Gol-Mohammadi”, on clinical symptoms of patients with functional dyspepsia with *H. pylori* infection: a double-blind randomized controlled trial

Protocol summary

Study aim

Determining the effect of "Ghors-Gol-Mohammadi" on clinical symptoms of patients with functional dyspepsia with *Helicobacter pylori*

Design

A controlled, double-blind, randomized, trial with parallel groups, phase 3, 70 patients. A computer random number table was used for randomization.

Settings and conduct

Participants referred to Gastrointestinal Diseases Clinic of Ayatollah Rouhani Hospital, Babol University of Medical Sciences, diagnosed with functional dyspepsia with *Helicobacter pylori* by the gastroenterologist (based on Rome IV), are introduced to researcher and if they met the inclusion criteria and informed consent are included in the study. This is a randomized double-blind clinical trial with two intervention groups of "Gors-Gol-Mohammadi pills" and "placebo" control. In each group, 35 participants are randomly allocated. Patients, health care providers, main researcher and statistical analyst are not aware of the type of intervention. The code sequence is hidden and the drug and placebo in the same dosage form are placed in the same sealed containers.

Participants/Inclusion and exclusion criteria

Inclusion: patients aged 18 to 65 years with symptoms of functional dyspepsia, diagnosis based on ROME IV criteria by gastroenterologist, with *Helicobacter pylori* infection. Exclusion: endoscopy with pathological findings, underlying diseases, history of abdominal surgery; malignancy. Pregnancy and breastfeeding. NSAIDs, herbal medicine, alcohol usage, smoking, history of allergy to formulation components

Intervention groups

Drug: Ghors-Gol-Mohammadi preparation consisting of *Rosa damascena*, licorice and *Nardostachys jatamansi* (2-1-1); placebo: tablets of corn starch mixed with 1% of

Ghors-Gol-Mohammadi powder

Main outcome variables

Severity of functional dyspepsia symptoms based on the total score of the GSRS questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221209056758N1**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

Registration date

2023-01-01, 1401/10/11

Registrant information

Name

Nader Behgam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of the effect of the poly-herbal preparation, "Ghors-Gol-Mohammadi", on clinical symptoms of patients with functional dyspepsia with H. pylori infection: a double-blind randomized controlled trial

Public title

Ghors-Gol-Mohammadi in functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with complaints of Functional dyspepsia
Diagnosis of functional dyspepsia based on ROME IV criteria by gastroenterologist
Helicobacter pylori infection positive test

Exclusion criteria:

History of peptic ulcer or reflux disease
Endoscopy with specific pathological findings
The presence of underlying diseases including heart failure, high blood pressure, kidney failure and uremic disease, cirrhosis
History of abdominal surgery
Any type of malignancy, history of chemotherapy and radiotherapy or exposure to radioactive radiation
Pregnancy and breastfeeding
Helicobacter pylori infection negative test
NSAIDs or any herbal medicine use
Smoking and alcohol consumption
History of any sensitivity to formulation components

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

First, based on the computerized random number table, the statistical consultant provides a list of numbers to the person preparing the drugs. After completing the drug preparation process, in the labeling stage, the containers are coded according to the series of numbers, and the list of numbers and groups is kept confidentially by the person preparing the drug until the end of the study. Permuted blocks of 4 are used to randomly allocate participants in two interventions groups, and the preparations are placed in envelopes in the order of random allocation created.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, the main researcher, the health care personnel who are responsible for the care of the patients, as well as the statistical analyzer, are blinded to the allocation of the two intervention groups to the drug or placebo. In this way, they are not aware of random codes, random allocation method and product type. Both products are prepared with the same dosage form and are placed in the same completely sealed containers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Health Research Institute, Babol University of Medical Sciences

Street address

GanjAfrooz St; Babol University of Medical Sciences, Babol

City

Babol

Province

Mazandaran

Postal code

Approval date

2022-11-27, 1401/09/06

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.182

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

The effect of «Ghors-Gol-mohammadi» on the severity of Functiona dyspepsia symptoms based on the total score of the GSRS questionnaire

Timepoint

At the beginning of the study, the second, fourth, sixth and eighth weeks from the beginning of the intervention

Method of measurement

Gastrointestinal Symptom Rating Scale questionnaire

Secondary outcomes

1

Description

The effect of "Ghors-Gol-mohammadi" on the severity of gastrointestinal symptoms in each of the 5 subgroups of symptoms of the Gastrointestinal Symptom Rating Scale questionnaire and the symptoms related to postprandial distress syndrome.

Timepoint

Before starting the intervention, the second, fourth, and eighth following weeks

Method of measurement

Gastrointestinal Symptom Rating Scale

2

Description

Score of quality of life

Timepoint

before the starting the intervention and at the eighth week

Method of measurement

Persian Nepean Quality of Life Questionnaire (NDI-10)

3

Description

Helicobacter pylori infection

Timepoint

Before the starting of the study and at the sixth week

Method of measurement

Urea breath test

Intervention groups

1

Description

Intervention group: Intervention group: GHors-Golmohammadi tablet consisting of *R. damascena* petals and dried licorice and *N. jatamansi* rhizomes, with a dose of 500 mg, three times a day (after meals) for 4 weeks. The drug is prepared by a specialist pharmacist in the pharmacy laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences. In order to prepare medicine, in each plant is dried and ground into powder. Rose, licorice and *jatamansi* plant powders are mixed in a weight ratio of 2:1:1 and mixed with suitable excipients and natural polymers. Then, the powder is moistened and granulated for a short time by means of a certain ratio of wetting agents. After drying and disinfecting, the granules are ground again, then, tablets are pressed. The tablet is determined by the amount of gallic acid and glycyrrhizic acid, and physicochemical and microbial control tests are

performed.

Category

Treatment - Drugs

2

Description

Control group: placebo. 3 times a day, for 4 weeks. Both groups are received standard treatments. The placebo is prepared by a specialist pharmacist in the pharmacy laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences. For the preparation of placebo, corn starch is used. In order to make its smell similar to the original medicine, it is mixed with the powder of Ghors-Gol-mohammadi at a ratio of 1%. Also, allowed and standard coloring agent is used to simulate the color of the original tablet. Each tablet contains 500 mg of powder. microbial limit tests are performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Nader Behgam

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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

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