Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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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

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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

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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

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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