# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Evaluation of the effect of the traditional poly-herbal preparation, “Ghors-e-Vard”, on clinical symptoms of patients with functional dyspepsia

## Protocol summary

**Study aim**
Evaluation of the effect of the traditional poly-herbal preparation, “Ghors-e-Vard”, on clinical symptoms of patients with functional dyspepsia with placebo

**Design**
This study is a randomized, double-blind, placebo-controlled clinical trial with randomized allocation in 4 blocks. Sample size 70, and trial phase is 3

**Settings and conduct**
Patients referred to Ayatollah Rohani Hospital, Babol University of Medical Sciences' Traditional Medicine and Hope Clinic, divided into intervention and control (35 in each). Gastrointestinal symptom severity (GSRS questionnaire score) will be assessed at baseline, and weeks 2, 4 and 8. Drug/placebo are coded randomly in identical packages. Patients, principal investigators are unaware of packages.

**Participants/Inclusion and exclusion criteria**
Inclusion: People aged 18-60 years, with functional dyspepsia (based on ROME IV syndrome) Exclusion: history of gastrointestinal ulcer or reflux disease with natural endoscopy without specific pathologic findings, underlying diseases including heart failure, hypertension, renal failure and uremic disease, cirrhosis; history of abdominal surgery; any malignancy or individuals NSAIDs are used, having a history of chemotherapy and radiotherapy or exposure to radiation. Use of any other herbal medicine; pregnancy and lactation; positive urea breath test for Helicobacter pylori infection

**Intervention groups**
Intervention group: To evaluate the therapeutic effect of Ghors-Vard on clinical symptoms of dyspepsia, patients will receive capsules containing Ghors-Vard three times daily (after meals) for 1 month. Control group: In order to compare the effect of the Ghors-Vard with the placebo effect on the clinical symptoms of functional dyspepsia, patients in the control group take placebo capsules three times daily (after meals) for 1 month.

**Main outcome variables**
Clinical symptoms of patients with functional dyspepsia

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200128046291N1**
Registration date: **2020-03-09, 1398/12/19**
Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**
Update count: **1**

**Registration date**
2020-03-09, 1398/12/19

**Registrant information**

**Name**
Hossein kerdarian

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 4274 0373

**Email address**
hosseinkerdarian@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-04-03, 1399/01/15

**Expected recruitment end date**
2020-06-19, 1399/03/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of the traditional poly-herbal preparation, “Ghors-e-Vard”, on clinical symptoms of patients with functional dyspepsia

**Public title**
The effect of the “Ghors-e-Vard” on functional dyspepsia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with Functional dyspepsia Ages 18 to 65 years
**Exclusion criteria:**
History of gastrointestinal ulcer or reflux disease with natural endoscopy with no specific pathologic findings, Underlying diseases including heart failure, hypertension, renal failure and uremic disease, cirrhosis History of abdominal surgery Any malignancy NSAIDs Use Having a history of chemotherapy and radiotherapy or exposure to radioactive radiation. Use of any other herbal medicine Pregnancy and lactation Positive urea breath test for Helicobacter pylori infection
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization is done by permuted block randomization. And medicines will be randomly allocated to patients in blocks with size four. Blinding will be double-blinded in the study. Patients will not be aware of their placement in the two groups and medications will be provided in identical forms for both groups. The researcher responsible for collecting baseline information and outcomes will also not be aware of the type of medication the patient is taking.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The drug and placebo are both prepared in identical non-transparent capsules and in completely similar cans and packages and coded according to the random table. None of the participants, principal investigator, health care personnel (physicians, nurses, etc.) responsible for patient care (etc.), data collectors and statistical analysts, will not be aware of patient received package and the coding.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Babol University of Medical Sciences
**Street address**
No. 47745-47176 , Ghasemi st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۱۷۶-۴۷۷۴۵
**Approval date**
2020-01-22, 1398/11/02
**Ethics committee reference number**
IR.MUBABOL.HRI.REC.1398.319

## Health conditions studied

**1**

**Description of health condition studied**
Functional dyspepsia
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Changes in clinical symptoms of functional dyspepcia
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale (GSRS)

## Secondary outcomes

**1**

**Description**
Epigastric pain
**Timepoint**
In days 0,14,30,60
**Method of measurement**

Gastrointestinal Symptom Rating Scale (GSRS)

**2**

**Description**
Heart burn
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale (GSRS)

**3**

**Description**
Early satiety
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale (GSRS)

**4**

**Description**
Feeling fullness after meals
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale (GSRS)

**5**

**Description**
Nausea
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale (GSRS)

**6**

**Description**
Burp
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale (GSRS)

**7**

**Description**
Flatulence
**Timepoint**
In days 0,14,30,60
**Method of measurement**
Gastrointestinal Symptom Rating Scale(GSRS)

**8**

**Description**
Quality of Life
**Timepoint**
In days 0,30
**Method of measurement**
Quality of Life Questionnaire (SF36)

## Intervention groups

**1**

**Description**
Intervention group: 35 patients with functional dyspepsia take 30 capsules of "Ghorse- vard" 3 times a day for 30 days after a meal. For small-lab-scale preparation of Ghors-Vard, in the cleanroom of the Traditional Pharmacy Lab of the Faculty of Traditional Medicine of Babol, under laboratory conditions, each of the dried herbs are individually milled, powdered, and passed through 60 mesh sieve. Then, according to traditional medicine sources, the required weight ratio of the powders is carefully mixed together and poured into mortar. The powder is then briefly moistened and granulated and then passed through a 40 mesh sieve. After drying and disinfecting the resulting granule in microwave in three 1 minute steps, the granules are re-milled and passed through sieve 60. After microbial control tests and quantification of phenolic compounds, the powder is filled by a capsule filler in 500 mg capsules. Both drug and control groups receive the standard treatment as well.
**Category**
Treatment - Other

**2**

**Description**
Control group: 35 patients with functional dyspepsia take 30 capsules of placebo 3 times a day for 30 days after a meal. For placebo preparation, in the clean room of the Traditional Pharmacy Lab of Babol Faculty of Traditional Medicine, under laboratory conditions, corn starch is disinfected by microwave in three minute steps, then is mixed with 1% of the Ghors-Vard powder mixed until the smell is a bit similar to the Ghors-Vard product. After microbial control tests, the powder is filled by a a manual capsule filling machine in 500 mg capsules.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ayatollah Rouhani Hospital
**Full name of responsible person**
Hossein Kerdarian
**Street address**
No. 47745-47176, Ghasemi st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۷۴۵-۴۷۱۷۶
**Phone**
+98 11 1222 9591

**Fax**
+98 11 1229 0181
**Email**
rohani@mubabol.ac.ir

**2**

**Recruitment center**
**Name of recruitment center**
Hope Clinic of Babol University of Medical Sciences
**Full name of responsible person**
Hossein Kerdarian
**Street address**
No. 47745-47176, Ganj Afrooz st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۷۴۵-۴۷۱۷۶
**Phone**
+98 11 3220 7751
**Email**
rohani@mubabol.ac.ir

**3**

**Recruitment center**
**Name of recruitment center**
Health clinic of Iranian medicine of Babol University of Medical Sciences
**Full name of responsible person**
Hossein Kerdarian
**Street address**
No. 47745-47176, Ganj Afrooz st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۷۴۵-۴۷۱۷۶
**Phone**
+98 11 3225 3526
**Email**
timbabol@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Dr. Reza Ghadimi
**Street address**
No. 47745-47176, Ghasemi st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۱۷۶-۴۷۷۴۵
**Phone**
+98 11 3219 9592
**Email**
info@mubabol.ac.ir
**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**
Hossein Kerdarian
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Traditional Medicine
**Street address**
No. 47745-47176, Ghasemi st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۱۷۶-۴۷۷۴۵
**Phone**
+98 11 3219 9592
**Email**
Hosseinkerdarian@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Zahra Memariani
**Position**
Assistant Professor
**Latest degree**
Ph.D.

**Other areas of specialty/work**
Pharmacy in traditional medicine
**Street address**
No. 47745-47176 , Ghasemi st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۱۷۶-۴۷۷۴۵
**Phone**
+98 11 3219 9592
**Email**
z.memariani@mubabol.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Hossein Kerdarian
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Traditional Medicine
**Street address**
No. 47745-47176 , Ghasemi st.
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۱۷۶-۴۷۷۴۵
**Phone**
+98 11 3219 9592
**Email**
Hosseinkerdarian@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
The data will be included in the thesis after being unrecognizable
**When the data will become available and for how long**
After completing the examinations, it will be fully inserted into the thesis
**To whom data/document is available**
All researchers will have access to the central library of Babol University of Medical Sciences
**Under which criteria data/document could be used**
Once inserted in the thesis it will be applicable
**From where data/document is obtainable**
Refer to the library of Babol University of Medical Sciences and after providing information
**What processes are involved for a request to access data/document**
Refer to the library of Babol University of Medical Sciences and after providing information
**Comments**