Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Formulation development of a combined tablet of Rosa damascena, and investigating its effectiveness on the clinical symptoms of functional dyspepsia patients: a randomized. Double-blind controlled trial

Protocol summary

Study aim
Determining the effect of the combined product of Vard tablet on the clinical symptoms of patients with Functional dyspepsia

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. A computer random number table was used for randomization

Settings and conduct
Individuals referred to the Gastrointestinal Diseases Clinic of Rouhani Hospital, Babol University of Medical Sciences, who are diagnosed as functional dyspepsia with H.pylori infection by the gastroenterologist's opinion (based on Rome IV) and were introduced to the researcher and if they met the entry criteria and informed consent are included in the study. This clinical trial is conducted in a double-blind randomized manner, with two intervention groups of "Vard tablet" and "placebo" control. In each group, 35 participants are randomly assigned. Patients, health care workers, researchers and statistical analysts are not aware of the type of intervention. The code sequence is hidden, and the drug and placebo are placed in the same sealed containers

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 65 years with symptoms of indigestion, diagnosis based on ROME IV criteria by gastroenterologist, with H.pylori infection
Exclusion criteria: endoscopy with pathological findings, underlying diseases, history of abdominal surgery; Any type of malignancy, history of chemotherapy and radiotherapy. Pregnancy and breastfeeding.NSAID use and any type of herbal medicine, smoking and alcohol, history of allergy to formulation components

Intervention groups
Intervention group: Vard tablet product consisting of Vard tablet, licorice and valerian(in a ratio of 2-1-1)
Placebo group: tablets prepared from corn starch mixed with 1% of Vard tablet powder

Main outcome variables
Severity of indigestion symptoms based on the total score of the GSRS questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241208063983N1**
Registration date: **2024-12-25, 1403/10/05**
Registration timing: **prospective**

Last update: **2024-12-25, 1403/10/05**
Update count: **0**

Registration date
2024-12-25, 1403/10/05

Registrant information

Name
behnam danesh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-11, 1403/10/22

Expected recruitment end date

2025-06-21, 1404/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation development of a combined tablet of Rosa damascena, and investigating its effectiveness on the clinical symptoms of functional dyspepsia patients: a randomized. Double-blind controlled trial

Public title

The effect of Rosa damascena combined tablet on functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 65 years with complaints of indigestion Diagnosis of functional dyspepsia based on IV Rome criteria by specialist digestion Positiveness of Helicobacter pylori infection

Exclusion criteria:

History of peptic ulcer Endoscopic with specific pathological findings 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 exposed to radioactive radiation, Pregnancy and breastfeeding, Negative test for Helicobacter pylori infection Use of NSAIDs and any type of herbal medicine Smoking and alcohol use, History of any allergy to product 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, patients are divided into two groups based on a computerized random number table. The statistics consultant provides a list of the order of assigning each number to two groups to the person preparing the drugs. In the labeling phase, the medicine containers are named only based on numbers. The list of numbers and groups will be given to the person who prepares the drugs to keep it confidential until the end of the study. In order to randomly allocate the two desired drugs, the quadruple drug blocking system is used at the time of drug administration for patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, the principal investigator, the health care personnel who are responsible for the care of the patients, as well as the statistical analyst are blinded to the allocation of the two intervention groups to drug or placebo. In this way, they are not aware of random codes, random allocation method and product type. Both products are prepared in the same pharmaceutical 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

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Ganj Afrooz St

City

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Mazandaran

Postal code

4717647745

Approval date

2024-03-16, 1402/12/26

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.216

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 "Rosa Damascena tablet" on the severity of indigestion symptoms based on the total score of the Gastrointestinal Symptom Rating Scale (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
GSRS Questionnaire

2

Description
The effect of "Rosa Damascena tablet "on the symptoms of early satiety and heart fullness from the Rome III Persian questionnaire.

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

Method of measurement
Farsi version of Rome III diagnostic questionnaire

Secondary outcomes

1

Description
Severity of gastrointestinal symptoms in each of the 5 subgroups of symptoms of the Gastrointestinal Symptom Rating Scale questionnaire and symptoms related to postprandial pain syndrome.

Timepoint
Before the start of the intervention, the second, fourth, and eighth weeks after the start

Method of measurement
GSRS questionnaire for the severity of gastrointestinal symptoms

2

Description
Sleep quality score

Timepoint
The beginning of the study, the fourth week, the eighth week

Method of measurement
Pittsburgh Sleep Quality Questionnaire (PSQI).

Intervention groups

1

Description
Intervention group:combined vard tablet consisting of rose and dried rhizomes of licorice and valerian, with a dose of 500 mg, three times a day (after meals) for four 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. The powders obtained of Rose, Licorice and Valerian plants are mixed in a ratio of 2:1:1 by weight and combined with suitable excipients and natural polymers. Then, the powder is moistened and granulated for a short time using a specific ratio of wetting agents. After drying and disinfection, the granules are ground again and then the tablets are pressed. The tablet is determined by the gallic acid and glycyrrhizic acid amount, and physicochemical and microbial control tests are performed.

Category
Treatment - Drugs

2

Description
Control group:Placebo Three pills a day (after meals) for four weeks. Both groups also receive standard treatment. Preparation of the placebo in the pharmaceutical laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences is prepared by a specialist pharmacist. For the preparation of placebo, corn starch is used. In order to make its smell similar to the original drug, it is mixed with the powder of vard tablets at a ratio of 1%. Also, permitted and standard food coloring is used to simulate the color of the original tablet. Each tablet contains 500 mg of powder. Microbial contamination control tests are performed. Placebo is a normal formulation that does not contain polymer components. Because the formula of the herbal tablet, in addition to the presence of the plant extract, is also examined in terms of the release mechanism of the extract.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Rouhani Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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

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Babol University of Medical Sciences
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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 more information

Study Protocol
No - There is not 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

No - There is not a plan to make this available