Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the Effectiveness and Safety of a Herbal Formulation Containing Trachyspermum ammi and Mentha spp. as an Adjunct to Pantoprazole, Compared with Placebo Plus Pantoprazole, on Gastric Ulcer Healing in Patients with Gastric Ulcer

Protocol summary

Study aim

Evaluation of the Efficacy and Safety of a Herbal Product Containing Trachyspermum ammi and Mentha as an Adjunctive Therapy to Pantoprazole, Compared with Placebo Plus Pantoprazole, in the Healing of Gastric Ulcers in Patients with Gastric Ulcer Disease

Design

This is a randomized, triple-blind, placebo-controlled, parallel-group Phase II trial. A total of 134 eligible patients will be allocated by block randomization to intervention and control groups (67 per group).

Settings and conduct

This clinical trial will be conducted at Loghman Hakim Hospital and, if needed, Modarres Hospital. Eligible patients will be randomized by block randomization into intervention and control groups after informed consent. The study will be triple-blind; participants, investigators, and outcome assessors will be blinded to allocation, with KDS syrup/placebo administered alongside pantoprazole and ulcer healing assessed by endoscopy after 3 months

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 16–75 years with Helicobacter pylori-negative gastric ulcer. Exclusion criteria: Pregnancy, breastfeeding, recent use of bismuth-containing drugs or antibiotics (within 2 weeks), GI bleeding requiring invasive intervention, gastric ulcer complications, ethanol consumption/substance abuse, and suspected gastric cancer.

Intervention groups

Intervention: Pantoprazole 40 mg daily plus KDS syrup 10 mL three times daily for 1 month. Control: Pantoprazole 40 mg daily plus placebo syrup 10 mL three times daily for 1 month.

Main outcome variables

The primary outcome variable is complete gastric ulcer healing at 3 months after treatment initiation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260727070386N1**
Registration date: **2026-09-03, 1405/06/12**
Registration timing: **prospective**

Last update: **2026-09-03, 1405/06/12**
Update count: **0**

Registration date

2026-09-03, 1405/06/12

Registrant information

Name

Hananeh Ghalavand

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-05, 1405/06/14

Expected recruitment end date

2028-02-20, 1406/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the Effectiveness and Safety of a Herbal Formulation Containing Trachyspermum ammi and Mentha spp. as an Adjunct to Pantoprazole, Compared with Placebo Plus Pantoprazole, on Gastric Ulcer Healing in Patients with Gastric Ulcer

Public title
Studying the effectiveness and safety of a herbal product containing ajwain and mint on healing gastric ulcers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Helicobacter pylori-negative gastric ulcer Age 16-75 years

Exclusion criteria:
Pregnancy Breastfeeding Use of bismuth-containing medications or antibiotics within the previous 2 weeks Gastrointestinal (GI) bleeding requiring invasive intervention Any complication of gastric ulcer Ethanol consumption or substance abuse Patients with suspected gastric cancer

Age
From **16 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **134**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to either the intervention or control group using block randomization. They will receive one of the following treatment regimens: • Control group: Pantoprazole 40 mg once daily plus placebo syrup, 10 mL three times daily for one month. • Intervention group: Pantoprazole 40 mg once daily plus KDS syrup, 10 mL three times daily for one month. Three months after the initial endoscopy, a follow-up endoscopy will be performed by the same gastroenterologist to reassess ulcer healing. Ulcer stage will be evaluated using the Sakita–Miwa Classification: • Active stage (A): A1 (fresh ulcer with inflamed and edematous margins) and A2 (reduced marginal inflammation). • Healing stage (H): H1 (initial epithelialization from the ulcer margin) and H2 (reduction in ulcer size with convergence of mucosal folds). • Scar stage (S): S1 (red scar, indicating complete healing with residual redness) and S2 (white scar, indicating complete healing with normal mucosal color). Complete healing will be defined as progression to S1 or S2, or complete disappearance of the ulcer. Treatment compliance and adverse events will be assessed by telephone at 2 weeks and 1 month after initiation of treatment. Statistical analysis will be performed using SPSS version 16. Data will be analyzed using the independent t-test and chi-square test, and a p-value < 0.05 will be considered statistically significant.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study will be conducted as a randomized, triple-blind clinical trial. The participants, investigators, and data analyst will be blinded to treatment allocation. The herbal formulation and placebo will be identical in appearance, color, odor, volume, packaging, and labeling, and will be identified only by unique codes. The randomization codes will be securely maintained by an independent person and will not be disclosed until completion of data analysis, except in the event of a medical emergency requiring unblinding .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti Medical Science University

Street address
School of Pharmacy, Shahid Beheshti University of Medical Sciences, No. 2660, Valiasr Street

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Postal code
1996835113

Approval date
2026-06-15, 1405/03/25

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1405.091

Health conditions studied

1

Description of health condition studied
Gastric ulcer

ICD-10 code
K25

ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
Percentage of patients with complete gastric ulcer healing at 3 months
Timepoint
Three months after treatment initiation
Method of measurement
Fallow-up upper gastrointestinal endoscopy

Secondary outcomes

1

Description
Percentage of patients with reduced gastric ulcer size after treatment
Timepoint
3 months after treatment initiation
Method of measurement
Upper gastrointestinal endoscopy and comparison with baseline ulcer size

2

Description
Percentage of patients with improved gastrointestinal symptoms after treatment
Timepoint
Two weeks and one month after treatment initiation
Method of measurement
Assessment and recording of gastrointestinal symptoms

3

Description
Percentage of patients requiring additional treatment during the study
Timepoint
During the study period
Method of measurement
Recording the need for additional treatment based on the patient’s clinical status

4

Description
Percentage of patients experiencing treatment-related adverse events
Timepoint
Two weeks and one month after treatment initiation
Method of measurement
Recording and assessment of patient-reported adverse events

Intervention groups

1

Description
Intervention group: Pantoprazole 40 mg daily + KDS syrup, 10 mL three times daily, for 1 month
Category
Treatment - Drugs

2

Description
Control group: Pantoprazole 40 mg daily + placebo syrup, 10 mL three times daily, for 1 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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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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