Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of ginger consumption on eradication of H.pylori, clinical symptoms, inflammatory factors, and oxidative stress in patients with peptic ulcer

Protocol summary

Study aim
To determine the effects of ginger consumption on eradication of H.pylori, clinical symptoms, inflammatory factors, and oxidative stress in patients with peptic ulcer

Design
A randomized, double-blinded, controlled clinical trial with a parallel group design of 42 patients. Random number table will be used for randomization.

Settings and conduct
42 eligible patients with peptic ulcer will randomly assign to consume four tablets daily each containing 500 mg of ginger or placebo for six weeks. Both groups will also receive the standard medical treatment in hospital. Patients' blood samples will be taken before and after the intervention to determine inflamation factors and oxidative stress markers and the two groups will also be compared in eradication of H.pylori and clinical signs. In this study participants and investigators will be blinded and concealment will be done by a third person.

Participants/Inclusion and exclusion criteria
People with a diagnosis of peptic ulcer and in the age range of 18-80 who are able to intake tablets orally and desire to participate in the study will be included in the study. While people having pregnancy or breastfeeding, any history of allergy to ginger, antibiotic use in the last 4 weeks,active alcohol consumption or alcohol, corticosteroid and anticoagulant use,Cardiovascular, liver, lung, kidney diseases ,malignancy, recent surgery will be excluded from the study.

Intervention groups
1- intrvention groups: receiving 2g of ginger daily in the form of 500mg tablets for 6 weeks; 2-Plasebo group: placebo tablets for 6 weeks

Main outcome variables
Eradication of H.pylori; serum IL-8 level, serum TAC level; degree of heartburn and stomach pain; length of indigestion; score of dyspepsia questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100524004010N35**
Registration date: **2023-02-08, 1401/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-08, 1401/11/19**
Update count: **0**

Registration date
2023-02-08, 1401/11/19

Registrant information

Name
Azita Hekmatdoost

Name of organization / entity
Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-08, 1401/11/19

Expected recruitment end date
2023-05-09, 1402/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of ginger consumption on eradication of H.pylori, clinical symptoms, inflammatory factors, and oxidative stress in patients with peptic ulcer

Public title
Evaluation of the effects of ginger consumption on eradication of H.pylori, clinical symptoms, inflammatory factors, and oxidative stress in patients with peptic ulcer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
General desire to practice the study Age over 18 years and less than 80 years Confirmation of H. pylori infection by stool antigen test or endoscopic pathology findings No antibiotic use in the last 4 weeks No active alcohol consumption or alcohol, corticosteroid and anticoagulant use No diseases Cardiovascular, liver, lung, kidney, malignancy Absence of recent surgery Absence of pregnancy or breastfeeding in women Absence of allergy to H pylori infection eradication regimen

Exclusion criteria:
Unwilling to continue the study Any allergic reaction to the supplements Consumption of less than 90% of supplements at the end of the study period

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomized into ginger group or placebo according to the table of random numbers at the beginning of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients won’t know if they are receiving the ginger or a placebo tablets and for double-blinding the study, the bottles containing the relevant tablets will be concealed as A and B by a third person at the beginning of the study, and none of the research team members will know the type of tablets received by each group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committie of the National Institute of Research and Food Industry

Street address
NO.7,West Arghavan Ave.,Farahzadi Blvd.,Qods Town

City
Tehran

Province
Tehran

Postal code
1981619573

Approval date
2023-01-21, 1401/11/01

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.057

Health conditions studied

1

Description of health condition studied
Peptic ulcer

ICD-10 code
K27

ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
H.Pylori eradication

Timepoint
8 week

Method of measurement
Endoscopy and Pathology

2

Description
Clinical Symptoms

Timepoint
8 week

Method of measurement
Questionnaire

3

Description
Anti-oxidant status

Timepoint
8 week

Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will take 2g of ginger daily in the form of four tablets each contains 500 mg of ginger (Product of Dine Company) orally for six weeks.
Category
Other

2

Description
Control group: will take four placebo tablets daily, which are similar in shape and taste to ginger tablet,orally for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani General Hospital
Full name of responsible person
Amir Sadeghi
Street address
Ayatollah Taleghani Educational Hospital,Araabi St.Yaman Ave,Chamran High Way,Tehran,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
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No.7,West Arghavan Ave.,Farahzad Blvd.,Qods Town
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a_hekmat2000@yahoo.com
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
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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