

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy evaluation of a formulation containing dried hydroalcoholic extract of *Trachyspermum ammi* (Ajwain) fruit in patients with *Helicobacter pylori*-associated gastric or duodenal ulcer

Protocol summary

Study aim

The Effect of Ajwain fruit extract in improving of Symptoms among Peptic ulcer caused by *Helicobacter pylori* patients and Its Comparison with Control Group

Design

Clinical trial with control and parallel groups, single-blinded, randomized, in 2-3 phases, has been conducted on 84 patients. RAND function in Excel software has been used for randomization purposes

Settings and conduct

The Clinical trial has been conducted in 2-3 phase on 84 patients with Peptic ulcer caused by *Helicobacter pylori* referring to gastroenterology clinic of Imam Khomeini Hospital. Signing the informed consent .At the end of treatment, the participants were required to score items on a 0-10 Likert Scale in terms of any observed improvement on the symptoms. The study is single-blinded and only the subjects have been put blind.

Participants/Inclusion and exclusion criteria

Age range of 18-70 years; Informed consent form; Confirmation of disease by ROME III criteria. Exclusion criteria: suffering from IBS and IBD; Having underlying diseases; Pregnancy or Breastfeeding; Allergy to product components; History of arbitrary use of antibiotics in the last 6 months. History of cancer.

Intervention groups

Oral prescription of a 100 mg capsule containing hydroalcoholic extract of Ajwain fruit and 400 mg of excipients, made in Pharmacognosy laboratory, implemented on 42 Peptic ulcer caused by *Helicobacter pylori* patients, three times a day for 2 weeks, Control group: Oral prescription of a 400 mg capsule containing excipients of the main medicine, including lactose powder, corn starch, sodium lauryl sulfate and talc powder, made in Pharmacognosy laboratory, implemented on 42 Peptic ulcer patients, three times a day for 2 weeks.

Main outcome variables

Abdominal pain, Diarrhea, Constipation, Bloating

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N17**

Registration date: **2023-08-27, 1402/06/05**

Registration timing: **prospective**

Last update: **2023-08-27, 1402/06/05**

Update count: **0**

Registration date

2023-08-27, 1402/06/05

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of a formulation containing dried hydroalcoholic extract of *Trachyspermum ammi* (Ajwain) fruit in patients with *Helicobacter pylori*-associated gastric or duodenal ulcer

Public title

The Effect of Ajwain fruit extract on Peptic Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range of 18-70 years
Signing the informed consent
Suffering from gastric and duodenal ulcers caused by *Helicobacter pylori*

Exclusion criteria:

Being afflicted with any underlying disease pregnancy
Being allergic to Apiaceae family plants. Lactation
periode Being afflicted with Irritable Bowel Syndrome and Inflammatory Bowel Disease. Have a history of arbitrary use of antibiotics for the treatment of peptic ulcers in the last 6 months. Have a history of cancer

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be done using graphpad.com and assigning letters A or B to the treatment or placebo groups and randomly distributing 84 people to the receiving group A or B. The software randomly assigns the letter A to 42 of the 84 numbers and the letter B to the 42 numbers. The people assigned to letter A will receive the medicine containing the extract of women and group B will receive the placebo.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only the participants were not informed about receiving either treatment/placebo capsules. Thus, the study is a single-blinded one. The subjects in this study were not either relatives or friends, thus they couldn't compare the impacts of receiving placebo/treatment. In addition, the appearance of the capsules and their containing package was exactly similar in both Intervention/control group and is not differentiated. All the study subjects received a good deal of information regarding the research plan and have

been presented to them .After being randomized through the use of statistical software package, treatment/placebo has been provided for them.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.077

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**

Abdominal pain

Timepoint

After intervention

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms(0=no improvement; 10= complete improvement)

2

Description

Bloating

Timepoint

After intervention

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms(0=no improvement; 10=complete improvement)

3

Description

Diarrhea

Timepoint

After intervention

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms(0=no improvement; 10=complete improvement)

4

Description

Constipation

Timepoint

After intervention

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms(0=no improvement; 10=complete improvement)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral prescription of a 100 mg capsule containing hydroalcoholic extract of Ajwain fruit, equal to 3 g of it and 400 mg auxiliary ingredients including lactose powder, corn starch, and talc powder and sodium lauryl sulfate, made in Pharmacognosy laboratory of Tehran's University of Medical Science, administered on 42 patients, three times a day (morning-noon-evening), for a 14 days.

Category

Treatment - Drugs

2

Description

Control group: Oral prescription of a capsule containing 400 mg of excipients of the main medicine including 350 mg lactose powder, 25 mg corn starch, 10 mg sodium lauryl sulfate and 15 mg talc powder, prepared in pharmacognosy laboratory of Tehran's University of Medical Science, administered in 42 patients, three times a day (morning-noon-evening), for a 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinics of Imam Khomeini hospital

Full name of responsible person

Dr. Mohammad Taher

Street address

Imam Khomeini Hospital, Keshavarz Blvd, Tehran, Iran

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1419733141

Phone

+98 21 6693 9009

Email

imamhospital@tums.ac.ir

Web page address

<http://ikhc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-chancellor of research and technology

Street address

Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz

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Tehran

Province

Tehran

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1417653761

Phone

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rmo@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mahdi Vazirian
Position
PhD of Pharmacognosy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacognosy Lab., Second Floor, New building,
Faculty of Pharmacy, In front of Oruji Alley, 16th Azar
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Person responsible for scientific inquiries

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Person responsible for updating data

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Mahdi Vazirian
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Demographic specification of patients, would be published, except their names and address. Primary

outcome of the patients would be published, too.

When the data will become available and for how long

Data would be available 6 months after publishing the results.

To whom data/document is available

Data would be available for researchers in academic and scientific organisation.

Under which criteria data/document could be used

Any types of usage of data is allowable, except using for manufacturing a product.

From where data/document is obtainable

Sending an E. mail to mehdivazirian@gmail.com

What processes are involved for a request to access data/document

After receiving E. mail, data would be sent within a week.

Comments