

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of Plantago major seed with placebo on GI symptoms in patients with erosive gastroduodenitis

Protocol summary

Study aim

Comparison of Plantago major seed with placebo on GI symptoms in patients with erosive gastritis or erosive duodenitis

Design

This study is a randomly-based phase3 clinical trial. 64 patients with erosive gastroduodenitis , which refer to the hospital of Rasoul Akram and the doctor's office, are randomly divided into two groups of intervention and control.

Settings and conduct

This study is done in double-blind way and contributors and clinicians are not aware of the drug. Patients referring to the Rasoul Akram hospital and the doctor's office ,64 people, are included in the study by entering conditions. Participants are randomly assigned to two intervention groups (32 people) and placebo (32 people). At first, 10 of each group were studied at pilot study.

Participants/Inclusion and exclusion criteria

Major inclusion criteria include: age of 20 to 60 years, those diagnosed erosive gastroduodenitis by endoscopy , negative test of Helicobacter pylori . Exclusion criteria are: pregnancy and lactation , cardiovascular disease, epilepsy , using anticoagulant medications, using a research drug in the past 30 days, any factor to reduce patient compliance and tolerance, such as alcohol and drug abuse, The existence of a severe illness that make performing endoscopy for them dangerous , severe bleeding , Malignancy,blood Coagulation Disorders , Zollinger Ellison syndrome , lung disease

Intervention groups

Intervention group (Plantago major seeds capsule): Members of the intervention group, twice a day, each time receiving two capsules of Plantago major seeds and 1 Pantoprazole 40 mg For 4 weeks placebo group (bread powder): members of this group, twice a day, each time 2 placebo capsules and 1 Pantoprazole 40mg for 4 weeks.

Main outcome variables

1- Severity of digestive symptoms 2- Frequency of digestive symptoms in the week

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190722044307N1**

Registration date: **2019-09-07, 1398/06/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-07, 1398/06/16**

Update count: **0**

Registration date

2019-09-07, 1398/06/16

Registrant information

Name

Fatemeh Fadaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8844 1032

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Plantago major seed with placebo on GI symptoms in patients with erosive gastroduodenitis

Public title

Plantago major L. in Erosive gastroduodenitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Erosive gastroduodenitis in endoscopy Negative Helicobacter pylori Test Written informed consent

Exclusion criteria:

pregnancy and lactation cardiovascular disease epilepsy anticoagulant medications use of a research drug in the past 30 day any factor to reduce patient compliance and tolerance, such as alcohol and drug abuse The existence of a severe illness that make performing endoscopy for them dangerous severe bleeding Coagulation Disorders Zollinger Ellison syndrome lung disease Malignancy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals were assigned to the intervention and control groups by using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. People in the study or patients, clinical caregiver, and researcher are unaware of the drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad Tehran Medical Sciences University ,Pharmaceutical sciences branch

Street address

Islamic Azad University, Pharmaceutical Sciences Branch, Yasman St , Yachchal St, ,Dr Shariati St , Tehran town

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Province

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Postal code

1941933111

Approval date

2019-04-22, 1398/02/02

Ethics committee reference number

IR.IAU.PS.REC.1398.010

Health conditions studied**1****Description of health condition studied**

Erosive gastroduodenitis

ICD-10 code

K29.9

ICD-10 code description

Gastroduodenitis, unspecified

Primary outcomes**1****Description**

Severity of gastrointestinal symptoms

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (28 days after the intervention)

Method of measurement

A questionnaire derived from ROME III and Visual Analogue Scale questionnaire

2**Description**

Frequency of symptoms in the week

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (28 days after the intervention)

Method of measurement

A questionnaire derived from ROME III

Secondary outcomes**1****Description**

Treatment Adverse reaction
Timepoint
End of the study
Method of measurement
Ask from patient

2

Description
Treatment satisfaction
Timepoint
End of the study
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Patients receive capsules of Plantago major seed (prepared in the Faculty of Traditional Medicine of Iran University of Medical Sciences) twice a day, each time receiving two capsules and one Pantoprazole 40mg , once a day For 4 weeks .
Category
Treatment - Drugs

2

Description
Control group: patients , twice a day, each time 2 placebo capsules and 1 Pantoprazole 40mg once a day , for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram 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

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Islamic Azad University
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

Islamic Azad University

Full name of responsible person

Fatemeh Fadaei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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