

# 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

##### Email address

f.fadaei.374@gmail.com

##### 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

**City**

Tehran

**Province**

Tehran

**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**  
Fatemeh Fadaei  
**Street address**  
Rasoul Akram Hospital , Mansouri St , Niayesh St , Satarkhan , Tehran town  
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## 2

**Recruitment center**  
**Name of recruitment center**  
Dr. Shahram Agah's office  
**Full name of responsible person**  
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**Street address**  
NO.1 , Ninth Street ,North Side Square Street ,Saadat Abad Street, Tehran town  
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## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Farshad Hashemian  
**Street address**  
Islamic Azad University, Pharmaceutical Sciences Branch, Yasman St , Yachchal St, ,Dr Shariati St , Tehran town  
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chancellor@iautmu.ac.ir

**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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## Person responsible for updating data

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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1449614535

**Phone**

## 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