Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison of the effect of Psyllium seed on the resolution and recurrence of Gastroesophageal Reflux Disease (GERD) with oral omeprazole in patients with functional constipation: A Randomized Clinical Trial study

Protocol summary

Summary

The patients with three years history of refractory gastroesophageal reflux disease (GERD) and functional constipation will undergo upper endoscopy. The patients (132 individuals) with esophagitis based on the Los Angeles classification will be participated in the study. According to random numbers table, the patients will be divided into two groups. One group will recieve omeprazole capsules (67 patients) and the other psyllium powder (65 patients). The two groups will be compared in terms of relieving GERD symptoms including burning sensation in the epigastrium and regurgitation and also the disease recurrences. The omeprazole group will receive twenty milligram omeperazole capsules half an hour before breakfast and dinner for two months. The population who will be treated with psyllium powder will be given five gram of the bulking agent solved in warm water, one hour before breakfast and dinner for two months, with a goal of bowel movements and a complete sense of defecation. All patients will be visited weekly for two months and questioned about the symptoms of GERD. Those who experience complete resolution of symptoms at the end of second month will be followed every week, for another 3 months, to evaluate the symptoms recurrences, given scores based on visual scales. Patients will be regarded as complete responders if they receive the score of zero, partial responders (scores 1-4) and Non-responders (≥ scores 5) who will be excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040315122N2**

Registration date: **2015-10-26, 1394/08/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-26, 1394/08/04

Registrant information

Name

Masoumeh Salari

Name of organization / entity

Mashhad University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2015-02-28, 1393/12/09

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effect of Psyllium seed on the

resolution and recurrence of Gastroesophageal Reflux Disease (GERD) with oral omeprazole in patients with functional constipation: A Randomized Clinical Trial study

Public title
Effect of Psyllium seed on the gastric reflux in patients with constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Symptomatic patients with minimum three years history of gastroesophageal reflux disease and functional constipation whose esophagitis in upper endoscopy will be confirmed. Exclusion criteria: History of or current gastrointestinal cancer; Hiatal hernia; Irritable bowel syndrome; Endocrine diseases (e.g., hypothyroidism); Drug-induced constipation; Psychological disorders; Cardiovascular diseases; Liver diseases; Renal diseases; Opiums abuse
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The assessor and the statistical analyst were unaware of the two groups. According to random numbers table, the patients will be divided into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashad University Of Medical Sciences
Street address
Goreyshi Building, Doktora Square, Daneshgah Street, Mashhad
City
Mashhad
Postal code

Approval date
2015-02-28, 1393/12/09
Ethics committee reference number
930965

Health conditions studied

1

Description of health condition studied
Gastro-esophageal reflux disease
ICD-10 code
K21.0
ICD-10 code description
Gastro-esophageal reflux disease with esophagitis

Primary outcomes

1

Description
Assessment reflux disease remission with constipation improvement
Timepoint
First day, 7th day, 14th day, 21th day, 28th day, 35th day,42th day, 49th day and 56th day after intervention.
Method of measurement
History of heart burn and regurgitation(clinical symptoms of GERD) was taken. Then the visual scale was used for evaluation.

Secondary outcomes

empty

Intervention groups

1

Description
Psyllium: The population treated with psyllium will be given 5 mg of the bulking agent solved in hot tap water one hour before breakfast and dinner with a goal of bowel movements and a complete sense of defecation twice daily.
Category
Treatment - Drugs

2

Description
Omeprazole: The omeprazole group will receive twenty-milligram omeprazole capsules half an hour before breakfast and dinner.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
Mousalreza Hosseini

Street address
Internal Department, Ghaem Hospital, Shariati Square, Ahmadabad Street, Mashhad

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Ghoreishi Building, Doktora Square, Danseshgah Street, Mashhad

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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
Vice chancellor for research, Mashad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty