

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 receive 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 omeprazole 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 (\geq 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2742

Email address

salarim@mums.ac.ir

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; Opioids 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

City

Mashhad

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

Mashhad University Of Medical Sciences

Full name of responsible person

Masoumeh Salari

Position

Assistant professor

Other areas of specialty/work

Street address

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

City

Mashhad

Postal code

Phone

+98 51 3801 2742

Fax

Email

salarim@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Mousalreza Hosseini

Position

Assistant Professor

Other areas of specialty/work

Street address

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

City

Mashhad

Postal code

0098

Phone

+98 51 3801 2742

Fax

Email

dr.hosseini@r@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Masoumeh Salari

Position

Assistant professor

Other areas of specialty/work

Street address

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

City

Mashhad

Postal code

Phone

+98 51 3801 2742

Fax

Email

salarim@mums.ac.ir

Web page address

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