

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Assessment of effect of Specific Dietary Interventions on severity of Dyspepsia in patients with Postprandial Distress Syndrom

Protocol summary

2015-08-06, 1394/05/15

Study aim

The effect of Specific Dietary Interventions in Postprandial Distress Syndrome.

Design

This study is a randomized without placebo-controlled.

Settings and conduct

This study include Two groups. Each group consist of Postprandial Distress Syndrome patients, One group with adlibitum diet (27 patients) and intervention group (29 patients) with special diet based on the recommendations of the Traditional Iranian Medicine for two weeks. During the subsequent 8 weeks, follow-up observations of primary and secondary outcomes performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Early Satiety or bothersome postprandial fullness more than 3 months.
Exclusion criteria: Patients with organic and systemic disorders; pregnancy and breast feeding.

Intervention groups

Males and females 18-75 years old who Referred to gastrointestinal Clinic in Ayatollah Taleghani Hospital.

Main outcome variables

severity of Functional Dyspepsia.

General information

Reason for update

Updates are performed to fill in the blanks

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050322049N1**

Registration date: **2015-08-06, 1394/05/15**

Registration timing: **prospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **1**

Registration date

Registrant information

Name

Fereshteh Nouri

Name of organization / entity

Shahed University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3333

Email address

fdr.nouri@gmail.com

Recruitment status

Recruitment complete

Funding source

Shahed University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

2017-04-08, 1396/01/19

Actual recruitment end date

2018-10-29, 1397/08/07

Trial completion date

2018-10-29, 1397/08/07

Scientific title

Assessment of effect of Specific Dietary Interventions on severity of Dyspepsia in patients with Postprandial Distress Syndrom

Public title

The effect of Specific Dietary Interventions in Postprandial Distress Syndrom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with 18-75 years old; Willing to cooperate; Early Satiety or bothersome postprandial fullness more than 3 months; Without Organic Disorders on physical examination; normal Endoscopic.

Exclusion criteria:

Patients with organic disorders; The use of Chemicals and Herbals any other medication; History of Abdominal surgeries; History of bloody diarrhea; Pregnancy and breast feeding; Lack of interest in work; Not sign the consent.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: blocking Randomization unit: individual In this method, each person was considered as a block. Because there were two groups of intervention (a) and control (b), it was determined based on quadruple blocks and by drawing blocks, and thus each person was placed in the intervention and control group. for example: A B A B B A A B B B A A ,..... Random allocation software was used for randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University of Medical Sciences

Street address

Opposite of Imam Khomeiny Shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2015-04-27, 1394/02/07

Ethics committee reference number

Shahed.REC.1393.45

Health conditions studied

1

Description of health condition studied

Functional dyspepsia

ICD-10 code

k30

ICD-10 code description

Indigestion

Primary outcomes

1

Description

Severity Assessment of Dyspepsia

Timepoint

At baseline, 2 and 8 weeks after starting the intervention

Method of measurement

The Gastrointestinal Symptom Scale

Secondary outcomes

1

Description

Postprandial fullness

Timepoint

At baseline, 2 and 8 weeks after starting the intervention

Method of measurement

The Gastrointestinal Symptom Scale

2

Description

Early Satiety

Timepoint

At baseline, 2 and 8 weeks after starting the intervention

Method of measurement

The Gastrointestinal Symptom Scale

3

Description

Bloating

Timepoint

At baseline, 2 and 8 weeks after starting the intervention

Method of measurement

The Gastrointestinal Symptom Scale

4

Description

Nausea

Timepoint

At baseline, 2 and 8 weeks after starting the intervention

Method of measurement

The Gastrointestinal Symptom Scale

5

Description

Belching

Timepoint

At baseline, 2 and 8 weeks after starting the intervention

Method of measurement

The Gastrointestinal Symptom Scale

Intervention groups

1

Description

Intervention group: special diet based on the recommendations of the Traditional Iranian Medicine for Two weeks. In this diet, based on the food groups of the new food guide pyramid with observing the principle of Variety and balance, cold and wet, heavy, slow-digesting or indigestible foods, and harmful to the stomach (based on reliable sources of traditional Persian medicine) are removed from patients' diets. Appropriate and equivalent are replaced in the same group. This diet are given to the patients in the intervention group for two weeks.

Category

Lifestyle

2

Description

Control group: continue previous diet without restriction

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Fereshteh Nouri

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Velenjak St., Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University of Medical Sciences

Full name of responsible person

Mohsen Naseri

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Tim Health care, Third Dashtestan Ave, Shariati Ave.

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3319118651

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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

Shahed 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

Shahed University of Medical Sciences

Full name of responsible person

Fereshteh Nouri

Position

Traditional Iranian Medicine PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Abdi

Position

Gastroenterologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

The description includes both the time period and the start date of the access

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In the form of publication of an article

From where data/document is obtainable

To the site of reputable domestic and foreign magazines

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

It depends on the acceptance and publication of the article in the intended journal

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahed University of Medical Sciences

Full name of responsible person

Fereshteh Nouri

Position

Traditional Iranian Medicine PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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