

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Assessment of effect of dietary modification in Bloating

Protocol summary

Summary

the purpose of the study: explanation of bloating according to traditional Iranian medicine. assessment of effect of dietary modification in bloating. inclusion criteria: Recurrent feeling of bloating or visible distension at least 3 days/month in the last 3 months. Insufficient criteria for a diagnosis of functional dyspepsia, irritable bowel syndrome, or other functional GI disorder. Criteria fulfilled for the last 6 months with symptom onset at least 6 months prior to diagnosis. exclusion criteria: abnormal abdominal examination. having acute or chronic gastrointestinal disease need surgery. gestation or lactation in women in gestational age. having disabling disease. existence of warning sign for example weight loss more than 4 kg in the last 3 month or blood in stool or melena or bloody vomiting in last 3 month. celiac diagnosis. lactase deficiency. lack of corporation or lack of interest in following the project. type of study: clinical trial. before after. sample size: 35 person. interventions of study: education of dietary modification. the duration of intervention: 4 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050633827N1**
Registration date: **2017-06-07, 1396/03/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-07, 1396/03/17

Registrant information

Name

زهرة مرتجى

Name of organization / entity

shahed university

Country

Iran (Islamic Republic of)

Phone

+98 5121

Email address

z.mortaji@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

shahed university

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effect of dietary modification in Bloating

Public title

effect of dietary modification in bloating

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Recurrent feeling of bloating or visible distension at least 3 days/month in the last 3 months. Insufficient criteria for a diagnosis of functional dyspepsia, irritable bowel syndrome, or other functional GI disorder. Criteria fulfilled for the last 6 months with symptom onset at least 6 months prior to diagnosis. exclusion criteria: abnormal abdominal examination. having acute or chronic gastrointestinal disease need surgery. gestation or lactation in women in gestational age. having disabling disease. existence of warning sign for example weight loss more than 4 kg in the last 3 month or blood in stool or melena or bloody vomiting in

last 3 month. celiac diagnosis. lactase deficiency. lack of corporation or lack of itnerest in following the project.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

shahed university

Street address

shahed university. khalij fars highway.

City

tehran

Postal code

9310

Approval date

2017-04-09, 1396/01/20

Ethics committee reference number

IR.Shahed.REC.1395.249

Health conditions studied

1

Description of health condition studied

bloating

ICD-10 code

K31

ICD-10 code description

Disease of oesophagus, stomach and duodenum

Primary outcomes

1

Description

bloating

Timepoint

start of study. 4 weeks after start of intervention

Method of measurement

questionnaire of gastrointestinal symptoms intensity

Secondary outcomes

1

Description

belching

Timepoint

start of study. 4 weeks after intervention

Method of measurement

questionnaire of gastrointestinal symptoms intensity

2

Description

acidify

Timepoint

start of study. 4 weeks after intervention

Method of measurement

questionnaire of gastrointestinal symptoms intensity

Intervention groups

1

Description

1 training session. The duration of each session: 30 min. Subjects: dietary modification based on Traditional Iranian Medicine. including: - Prohibition of drinking water a half hour before meals, while eating, up to an hour after eating. -chewing each bite 30 times. - prohibition of eating salad or jelly with meals. -Reducing the amount of food at each meal. These should run for 4 weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

mostafa khomeini hospital

Full name of responsible person

zohreh mortaji

Street address

italia street, keshavers blv

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shahed university

Full name of responsible person

dr. zahra kiasalari

Street address

khalij fars highway

City

tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

shahed university

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

shahed university

Full name of responsible person

zohreh mortaji

Position

resident of traditional medicine

Other areas of specialty/work

Street address

khalij fars highway

City

tehran

Postal code

9310

Phone

+98 21 5121

Fax

Email

z.mortaji@shahed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

shahed university

Full name of responsible person

dr. elham emaratkar

Position

assistant professor

Other areas of specialty/work

Street address

khalij fars highway

City

tehran

Postal code

9310

Phone

+98 21 5121

Fax

Email

emaratkar@shahed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

shahed university

Full name of responsible person

zohreh mortaji

Position

resident of traditional medicine

Other areas of specialty/work

Street address

khalij fars highway

City

tehran

Postal code

9310

Phone

+98 21 5121

Fax

Email

zohreh.mortaji@gmail.com

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