

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effects of yogurt containing probiotics in treating gastroesophageal reflux disease: a randomized clinical trial

Protocol summary

Study aim

The effect of probiotic yogurt consumption on Gastroesophageal reflux disease

Design

120 patients will participate in the study, in three groups: non-probiotic yogurt, probiotic yogurt and omeprazole group with 40 patients in each group. Randomization will be based on Permuted Block Randomization

Settings and conduct

A clinical trial study (three-blinded for our cohorts), between 2020-21, on patients older than 18 years referred to Gastroenterology Clinics of North Khorasan with gastroesophageal reflux disease (Gastroenterology and Liver). Three treatment modalities (prebiotic yogurt, plain yogurt, omeprazole) are written on cardboards by codes and enclosed in envelopes and will be delivered to the specialist physician in a completely randomized manner.

Participants/Inclusion and exclusion criteria

-Inclusion criteria: The patient be literate or someone helps him/her in filling the questionnaires; Patients should be geographically accessible -Exclusion criteria: Age less than 18 years; Allergy to dairy products; Pregnancy; History of gastrointestinal malignancy

Intervention groups

There are three treatment groups with three treatments. The first group will consume normal yogurt, the second group will take omeprazole, and the third group will use prebiotic yogurt.

Main outcome variables

evaluation of quality of life Intensity of reflux

General information

Reason for update

Modifying the sample size and secondary outcome

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044653N4**

Registration date: **2020-01-30, 1398/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-29, 1402/01/09**

Update count: **1**

Registration date

2020-01-30, 1398/11/10

Registrant information

Name

Maryam Rameshrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7182

Email address

mrameshrad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2020-05-30, 1399/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of yogurt containing probiotics in treating gastroesophageal reflux disease: a randomized clinical trial

Public title

Evaluating the effects of yogurt containing probiotics in

treating gastroesophageal reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient be literate or someone helps him/her in filling the questionnaires Patients should be geographically accessible

Exclusion criteria:

Age less than 18 years Allergy to dairy products
Pregnancy History of gastrointestinal malignancy History of gastric and esophageal surgery and small bowel bypass Liver and kidney and heart dysfunction
Concomitant use of NSAIDs and aspirin for up to one week before the study Anticancer or antibiotic use during 4 weeks before referral and participation in this study No anti-acid, hydrogen pump inhibitors, H2 receptor inhibitors in two groups of yogurt recipients during the study Receiving bisphosphonate, cortisone, potassium chloride or iron tablets concurrently in the study Patient's compliance be less than 80% (self-reported by patient)

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients were randomized based on block permutation methods (permuted block randomization) into the three treatment groups (2 groups (probiotic yogurt and regular yogurt) and a control group). Based on the result of randomization by Permuted Block Randomization and R software, patients are allocated to groups sequentially in order of their meeting. The yogurts, both probiotic and simple, will be provided in the same shape single dose containers without any type definer and will be introduced to the drug distributor with unmeaning code.

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

Ethics Committee of North Khorasan University of Medical Sciences

Street address

Bojnourd - Behind Imam Ali Hospital - Deputy of Research and Technology

City

bojnourd

Province

North Khorasan

Postal code

9418655459

Approval date

2019-11-16, 1398/08/25

Ethics committee reference number

IR.NKUMS.REC.1398.084

Health conditions studied

1

Description of health condition studied

Gastroesophageal reflux disease (GERD)

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

effect on the GERD severity

Timepoint

Baseline, one month and tow months later

Method of measurement

The Gastroesophageal Reflux Disease-Health Related Quality of Life instrument (related to typical symptoms)

2

Description

Effect on the severity of GERD atypical symptoms

Timepoint

Baseline, one month and tow months late

Method of measurement

Reflux Symptom Index and Disease Specific Quality of Life Index questionnaires (related to atypical symptoms)

Secondary outcomes

1

Description

Assessment of quality of life

Timepoint

At baseline, one month and tow months later

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Ordinary yogurt

Category

Treatment - Other

2

Description

Intervention group: Probiotics yogurt

Category

Treatment - Other

3

Description

Control group: Omeprazole

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal Clinic of Imam Hassan Hospital

Full name of responsible person

Dr. Seyyed Javad Pour Naghi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

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Grant name

Grant, Faculty Member of Bojnourd University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Seyed Javad Pournaghi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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