

# 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

Bojnourd - Imam Hassan Hospital - Class 4

##### City

Bojnourd

##### Province

North Khorasan

##### Postal code

9418655459

##### Phone

+98 58 3151 4241

##### Email

pournaghij861@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bojnourd University of Medical Sciences

##### Full name of responsible person

Dr. Kaveh Hojjat

##### Street address

Shahriar

##### City

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##### Province

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##### Email

S.Kavehhojjat1@gmail.com

#### 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

Gastrointestinal

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Bojnourd - Imam Hassan Hospital - 6th floor

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## Person responsible for scientific inquiries

#### Contact

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Assistant Professor  
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## Person responsible for updating data

### Contact

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Bojnourd University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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rameshrm2@mums.ac.ir

## 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