

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluation of probiotic usage on the intestinal microbiota diversity in patients with celiac disease; a clinical trial study

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

To evaluation of probiotics usage on the intestinal microbiota diversity in patients with celiac disease.

Last update: **2019-10-29, 1398/08/07**

Update count: **0**

#### Design

Patients with celiac disease who had been on gluten-free diet for more than one year and were divided into two groups of probiotic or placebo consuming patients and examined for 3 months.

#### Registration date

2019-10-29, 1398/08/07

#### Registrant information

##### Name

Mona Soheilian Khorzoghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8808 1907

##### Email address

m.sohailian@yahoo.com

#### Settings and conduct

The study included two groups: 16 placebo recipients, 15 probiotic recipients under gluten-free diet GFD. Stool samples and blood samples collecting, probiotics and placebo will be prescribed to people with celiac disease 3 times a day for 3 months. After 3 months, stool and blood samples of individuals with celiac disease will be collected again, DNA extracted from stool samples will be done, Primer pairs will be designed, Real-time-PCR will be Performed, Separation of whole blood serum samples: Data will be analyzed using SPSS software.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

patients with CD, aged between 15-90 years, adhering to a strict GFD. Exclusion criteria were pregnancy, acute or chronic diseases, Crohn, colitis ulcerative, short bowel syndrome disease, consuming alcohol and steroid drugs, ingestion of antibiotics and anti-inflammation nonsteroid drugs at least 1 month prior to study.

#### Expected recruitment start date

2019-05-04, 1398/02/14

#### Expected recruitment end date

2020-05-03, 1399/02/14

#### Actual recruitment start date

2019-05-04, 1398/02/14

#### Actual recruitment end date

2020-05-03, 1399/02/14

#### Trial completion date

2020-05-03, 1399/02/14

#### Intervention groups

Probiotic and placebo

#### Main outcome variables

The Effect of Probiotics on the Symptoms of Patients with Celiac Disease

#### Scientific title

Evaluation of probiotic usage on the intestinal microbiota diversity in patients with celiac disease; a clinical trial study

#### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20171225038063N1**

Registration date: **2019-10-29, 1398/08/07**

#### Public title

Evaluation of probiotic usage on the intestinal microbiota diversity in patients with celiac disease; a clinical trial

study

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patient under gluten-free diet(GFD) Confirmed having celiac disease based on serology and pathology tests  
**Exclusion criteria:**  
Pregnancy People with the disease Crohn, colitis ulcerative, short bowel syndrome, mouth and stomach surgery, cancer and hepatitis Use of steroids, antibiotics, and nonsteroidal anti-inflammatory drug 4 weeks before the study Alcohol consumption

**Age**  
From **15 years** old to **90 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **31**  
Actual sample size reached: **31**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The target population of this study including 31subjects with the celiac disease under gluten-free diet GFD who will be randomly assigned to two groups of probiotics (n = 15) or placebo (n = 16).

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participants, main investigators, patient care providers, doctors, supervisors, data collectors and people who evaluate the outcome.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
Use of native probiotics in Iranian patients with celiac disease for the first time

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

#### Street address

Velenjak Ave,Taleghani Hospital,Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1985714711

#### Approval date

2017-03-13, 1395/12/23

#### Ethics committee reference number

IR.SBMU.RIGLD.REC.1395.114

## Health conditions studied

### 1

#### Description of health condition studied

Celiac

#### ICD-10 code

K63.9

#### ICD-10 code description

Disease of intestine, unspecified

## Primary outcomes

### 1

#### Description

Fold change in abundance of intestinal Microbiota of patients with celiac disease

#### Timepoint

3 months

#### Method of measurement

Real Time PCR

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Probiotic capsule, capsule formulation containing: the Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus strains, each capsule containing 1000000000 colonies, 3 capsules per day, Duration 3 months, produced by the Zist Takhmir company

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo capsule,Capsule formulation

containing Fructooligosaccharide as Prebiotic, Lactose, Mg stearate, talc , 3 capsule per day, Duration 3 months ,Product of zist takhmir company

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Taleghani Hospital

**Full name of responsible person**

Mohamad Rostami Nejad

**Street address**

Yaman st,Velenjak Region, Chamran High Way

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m.rostamii@gmail.com

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohamad Rostami Nejad

**Street address**

Yaman St. Velenjak Region, Chamran High Way,

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**Postal code**

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**Phone**

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Rostami Nejad

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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Velenjak, Taleghani hospital

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohamad Rostaminejad

**Position**

Asistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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## Person responsible for updating data

m.sohailian@yahoo.com

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mona Soheilian Khorzoghi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Microbiology

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No.36,Arghavan 2 Ave,Pardisan Residential Complex  
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**Email**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Patient information is kept confidential and will not be published

**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**

No - There is not 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**

No - There is not a plan to make this available