

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)

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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 31 subjects 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

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Yaman st,Velenjak Region, Chamran High Way

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mohamad Rostaminejad

Position

Asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Name of organization / entity

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Full name of responsible person

Mona Soheilian Khorzoghi

Position

Student

Latest degree

Master

Other areas of specialty/work

Microbiology

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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