

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

A study of the effect of Synbiotic Supplement in Gastrointestinal Symptoms and Quality of Life in Patient with Celiac Disease: a randomized double blinded clinical trial

Protocol summary

Gastrointestinal symptoms, Quality of Life

Study aim

Determining the effect of synbiotic supplementation on gastrointestinal symptoms and quality of life in patients with celiac disease

Design

This study is a parallel randomized double-blind clinical trial, phase 3 on 108 patients who are divided into intervention and control groups. The "random block" method will be used for randomization. We generate blocks with Random Allocation Software.

Settings and conduct

This study was performed on 108 people with celiac disease referred to the celiac clinic of Bustan clinic in Kermanshah. Patients will be divided into two groups based on random allocation. The first group of patients who will receive synbiotic product in the amount of 2 capsules per day and the second group who will receive placebo as a control group. Evaluations are performed in two stages at the beginning and end of the study (12 weeks later). For blinding, placebo and synbiotic supplements are placed in the same color capsules and drug packages and will receive a special code from the manufacturer. The codes will remain with the manufacturer until the end of the study to blind researchers and patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to cooperate Definitive diagnosis of celiac disease Age over 18 years and less than 65 years Do not take any dietary supplements Do not suffer from chronic diseases Exclusion criteria: Allergic reaction to the supplement Consume less than 80% of the drug Changes in the type of daily medication such as Antacids, Antibiotics, PPI, H2 blocher Failure to follow a gluten-free diet Pregnancy and lactation

Intervention groups

Patients with celiac disease

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210717051916N1**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **prospective**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Mahdis Jahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of the effect of Synbiotic Supplement in Gastrointestinal Symptoms and Quality of Life in Patient with Celiac Disease: a randomized double blinded clinical trial

Public title

A study of the effect of Synbiotic Supplement in Gastrointestinal Symptoms and Quality of Life in Patient with Celiac Disease: a randomized double blinded clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of celiac disease based on test results and specialist diagnosis

Exclusion criteria:

pregnancy- Breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized parallel double-blind clinical trial. Randomization will be done using block randomization. We produce 27 blocks (each block contains 4 codes) by Random Allocation Software. All 4 people correspond to one block, respectively. The blocks are produced by a statistician and it will be made available to the nutritionist who assigns the individuals. The hiding mechanism is such that the statistical consultant generates a random sequence, the student registers individuals and a nutritional partner assigns individuals to intervention groups. The codes of the assigned individuals are only with the nutritionist who does not participate in the measurements.

Blinding (investigator's opinion)

Double blinded

Blinding description

The student registers people. The blocks are produced by a statistician and will be provided to a nutritionist who assigns individuals. The nutritionist is not involved in the measurements. The statistician who determines the blocks will also be blinded to avoid bias in the analysis. For blinding, placebo and synbiotic supplements are placed in the same color capsules and drug packages. Drug packages in the manufacturer will have a special

code. The codes will remain with the manufacturer until the end of the study to blind researchers and patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Parastar Blvd., Imam Reza Hospital

City

Kermanshah

Province

Kermanshah

Postal code

75333 67427

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.KUMS.MED.REC.1400.122

Health conditions studied**1****Description of health condition studied**

Patients with celiac disease

ICD-10 code

K90.0

ICD-10 code description

Celiac disease

Primary outcomes**1****Description**

Gastrointestinal symptoms of patients before and after taking the supplement

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later

Method of measurement

Gastrointestinal Symptom Rating Scale questionnaire (GSRS)

Secondary outcomes

1

Description

Quality of life of patients

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later

Method of measurement

The celiac disease quality of life questionnaire (CDQOL)

Intervention groups

1

Description

Intervention group: To individuals in the intervention group, Familact synbiotic capsules are given from Zist Takhmir pharmaceutical company. each capsule of which contains 500 mg of synbiotic product. People take 2 capsules daily for 12 weeks. Each synbiotic capsule contains beneficial bacterial strains by counting 10⁹ CFU (Colony-forming unit) and prebiotics as follows: Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus, Fructooligosaccharides (FOS). In the fasting state, all participants will have anthropometric assessments, including height, weight, body mass index, hip circumference, and waist circumference. In order to be aware of the patient's compliance with the supplement and possible side effects of the supplement, patients are contacted on a weekly basis. The rate of supplementation by patients is assessed through telephone calls as well as through the return of packages containing capsules. Consumption of less than 80% of synbiotic capsules at the end of 12 weeks is considered as low adherence. At the end of the supplementary support period (12 weeks), the assessments (except for patients' height) will be performed again. In these patients, quality of life, severity of gastrointestinal symptoms and adherence to gluten-free diet will be assessed by relevant questionnaires at the beginning and end of the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Celiac clinic of Kermanshah Bustan Clinic

Full name of responsible person

Shima Rostami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mehdi Zobeiri

Position

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