Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 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

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
Gastrointestinal symptoms, Quality of Life

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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+98 83 3843 8073

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jahani.mahdis@yahoo.com

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
Internal Medicine
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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