# 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)

**Phone**
+98 83 3843 8073

**Email address**
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
**Street address**
Parastar Blvd., Bustan Clinic
**City**
kermanshah
**Province**
Kermanshah
**Postal code**
67427-75333
**Phone**
+98 83 3710 6105
**Email**
irhk@kums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Mehdi Zobeiri
**Street address**
Parastar Blvd., Kermanshah University of Medical Sciences
**City**
Kermanshah
**Province**
Kermanshah
**Postal code**
67427-75333
**Phone**
+98 83 3835 8943
**Email**
irhk@kums.ac.ir
**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
**Street address**

Parastar Blvd., Imam Reza Hospital

**City**
kermanshah

**Province**
Kermanshah

**Postal code**
75333 - 67427

**Phone**
+98 83 3427 6300

**Email**
mehdizobeiri@yahoo.com

## Person responsible for scientific 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

**Street address**
Parastar Blvd., Imam Reza Hospital

**City**
kermanshah

**Province**
Kermanshah

**Postal code**
75333 - 67427

**Phone**
+98 83 3427 6300

**Email**
mehdizobeiri@yahoo.com

## Person responsible for updating data

**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

**Street address**
Parastar Blvd., Imam Reza Hospital

**City**
kermanshah

**Province**
Kermanshah

**Postal code**
75333 - 67427

**Phone**
+98 83 3427 6300

**Email**
mehdizobeiri@yahoo.com

## 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