# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Evaluating the effect of administration of Lactocare® probiotic on gasterointestinal symptoms and Anti-Ttg antibody in patients with celiac disease: Randomized controlled Clinical trial

## Protocol summary

**Study aim**

Evaluating the effect of administration of Lactocare® probiotic on gastrointestinal symptoms and Anti-Ttg antibody in patients with celiac disease

**Design**

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 100 patients. A block method used for randomization.

**Settings and conduct**

All patients with celiac disease over 18 years of age registered in the Golestan Gastroenterology and Liver Research Center registry who meet the inclusion criteria are invited to participate in the study. After obtaining consent from all patients at the Gastroenterology and Liver Research Center, using the Celiac Disease symptom Index (CSI) questionnaire, the severity and extent of their disease symptoms are recorded and the tissue transglutaminase antibody titer (Anti-Ttg) is also recorded. the study is double-blind both patients nor doctors will not know about the group in which the patient is examined.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Confirming the presence of celiac disease with a small intestine biopsy and anti-tissue transglutaminase antibody titer measurement (Anti TTG) Age over 18 years exclusion criteria: Any recent infections Taking drugs that affect the immune system Recent gastrointestinal surgery Taking NSAID painkillers or antibiotics in the last 6 weeks Any comorbidity Pregnancy and breastfeeding addiction

**Intervention groups**

The intervention group will use the Lactocare symbiotic for 6 weeks, 2 capsules every day with an interval of 12 hours, and along a gluten-free diet. The control group received the placebo or 6 weeks, 2 capsules every day with an interval of 12 hours along with a gluten-free diet.

**Main outcome variables**

Celiac disease symptom index (CSI) questionnaire and tissue transglutaminase antibody titer (Anti-Ttg)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20080921001264N12**
Registration date: **2023-01-24, 1401/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-24, 1401/11/04**
Update count: **0**

**Registration date**

2023-01-24, 1401/11/04

**Registrant information**

**Name**
Sima Besharat
**Name of organization / entity**
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-01-20, 1401/10/30

**Expected recruitment end date**

2023-04-19, 1402/01/30

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluating the effect of administration of Lactocare® probiotic on gasterointestinal symptoms and Anti-Ttg antibody in patients with celiac disease: Randomized controlled Clinical trial

**Public title**
Evaluating the effect of administration of Lactocare® probiotic on gasterointestinal symptoms and Anti-Ttg antibody in patients with celiac disease: Randomized controlled Clinical trial
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Confirmation of celiac disease with small intestine biopsy Measurement of antibody titer against tissue transglutaminase (Anti TTg) Age above 18 years
**Exclusion criteria:**
Any recent infections Concomitant inflammatory bowel disease (IBD) Immune deficiency (acquired or non-acquired) Taking drugs that affect the immune system (immune suppressors and stimulants) Recent GI surgery Taking NSAID painkillers or antibiotics in the last 6 weeks Having cancer or being HIV positive Cardiovascular diseases, glands, kidney, liver, neurological or mental malignancy Pregnancy and breastfeeding Alcohol and drug addiction Participation in another similar study within the last 6 months unwillingness to take probiotics patient being out of reach
**Age**
From **18 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **98**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method: In order to randomize the samples, we use the block method with blocks of four. In this way, one of the following blocks is chosen randomly (for example, with a dice) and according to the order of those samples, We assign two groups. And the fourth sample will be assigned to the group receiving the supplements. Then, for the next four samples, we will randomly select a block and make the allocation according to it, and this process will continue until the end of the sampling. If a woman 35-year-old with a body mass index of 29 is in the target group, there will be another patient with similar characteristics in the control group, and the cut-off for these values has not been defined, and it will be tried to compare the patients of the two groups with a reasonable standard deviation in These variables are similar.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The study is double-blind, so that all patients and doctors evaluating the interventions designed in the study or the outcomes after carrying out the plan will not know about the group in which the patient is examined. All interventions in both groups will be designed similarly and the procedure will be the same on all samples in all groups. The drugs used will also be supplied in the same form and packaging so that it is not possible to identify the study group during the study process.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethical committee of Golestan University of Medical Sciences
**Street address**
Golestan University of Medical Sciences-Hircan Boulevard-Gorgan city-Golestan province-
**City**
Gorgan
**Province**
Golestan
**Postal code**
4918936316
**Approval date**
2022-12-25, 1401/10/04
**Ethics committee reference number**
IR.GOUMS.REC.1401.481

## Health conditions studied

### 1

**Description of health condition studied**
celiac disease
**ICD-10 code**
K90.0
**ICD-10 code description**
Celiac disease

## Primary outcomes

**1**

**Description**
the severity and extent of disease symptoms
**Timepoint**
The beginning of the study and 6 weeks after the start of the study
**Method of measurement**
CSI ( celiac symptom index ) questionnaire

**2**

**Description**
Tissue transglutaminase antibody titer (Anti-Ttg)
**Timepoint**
The beginning of the study and 6 weeks after the start of the study
**Method of measurement**
titer Anti-TTG

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Including 49 patients, they will use 2 capsules of Lactocar probiotic every day for 6 weeks, with an interval of 12 hours, and along with this medicine, they will follow a gluten-free diet.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Including 49 patients, they will use 2 capsules of placebo every day for 6 weeks, with an interval of 12 hours, and along with this medicine, they will follow a gluten-free diet.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Golestan Research Center of Gastroenterology and Hepatology
**Full name of responsible person**
Taghi Amiriani
**Street address**
Third floor, Abbassi Heart complex, Golestan Research Center of Gastroenterology and Hepatology, Sayyad Hospital, Gorgan city
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## Sponsors / Funding sources

**1**

**Sponsor**
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Gorgan University of Medical Sciences
**Full name of responsible person**
Gholamreza Roshandel
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Zist Takhmir pharmaceutical company
**Proportion provided by this source**
100
**Public or private sector**
Private
**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**
Gorgan University of Medical Sciences
**Full name of responsible person**
Taghi Amiriani
**Position**
Associate professor

**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All deidentified data will be available in case of any requests from other researchers.
**When the data will become available and for how long**
Data availability will be started after publishing the full paper until 6 months later.
**To whom data/document is available**
Data will be available for all academic and also pharmaceutical researchers requires.
**Under which criteria data/document could be used**
Data will available for those with a clear history of research.
**From where data/document is obtainable**
Data will be available by direct request from the PI (Dr.Amiriani) by E-mail.
**What processes are involved for a request to access data/document**
It will be available after about one months.
**Comments**