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

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Golestan University of Medical Sciences
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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-
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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
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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
Name of organization / entity
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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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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