

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A pilot study on the safety and effectiveness of celiac support capsule on clinical symptoms in patients suffering from celiac disease

Protocol summary

Study aim

Evaluating the protective effects of celiac support capsules in new celiac patients

Design

Phase 2 non-randomized, open-label clinical trial with one group on 12 patients

Settings and conduct

The study will be conducted in Clinics affiliated to Mashhad University of Medical Sciences. Patients suffering from Celiac receive one Celiac Support capsule (every 6 hours) for 3 months 30 minutes before eating a diet containing gluten.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from celiac disease, not pregnant, age between 5 to 30 years, not suffering from other diseases, normal liver and kidney status Exclusion criteria: Occurrence of drug allergy, occurrence of clinical symptoms of celiac disease within 48 hours

Intervention groups

Patients suffering from Celiac receive one Celiac Support capsule (every 6 hours) for 3 months 30 minutes before eating a diet containing gluten.

Main outcome variables

Clinical symptoms such as diarrhea, urticaria, abdominal pain and bloating, nausea, vomiting, dyspepsia, abdominal pain, headache, fatigue, skin rashes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N17**

Registration date: **2023-06-22, 1402/04/01**

Registration timing: **prospective**

Last update: **2023-06-22, 1402/04/01**

Update count: **0**

Registration date

2023-06-22, 1402/04/01

Registrant information

Name

Vahid Reza Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2264

Email address

askariv941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A pilot study on the safety and effectiveness of celiac support capsule on clinical symptoms in patients suffering from celiac disease

Public title

A pilot study on the celiac support capsule in patients suffering from celiac disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having celiac disease Age between 5 to 30 years Not

suffering from other diseases Normal liver and kidney status Not pregnant
Exclusion criteria:
The occurrence of drug allergy Occurrence of clinical symptoms of celiac disease within 48 hours

Age

From **5 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical sciences ethical committee

Street address

Faculty medicine, Ferdowsi complex, Vakil Abad Blvd, Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.022

Health conditions studied

1

Description of health condition studied

Celiac

ICD-10 code

K90

ICD-10 code description

Intestinal malabsorption

Primary outcomes

1

Description

Clinical symptoms such as diarrhea, urticaria, abdominal pain and bloating, nausea, vomiting, dyspepsia, abdominal pain, headache, fatigue, skin rashes

Timepoint

Weekly

Method of measurement

Checklist

Secondary outcomes

1

Description

Anti-transglutaminase antibody

Timepoint

At the beginning of the study and after 3 months of treatment

Method of measurement

Laboratory kit

2

Description

Antiendomysial antibody

Timepoint

At the beginning of the study and after 3 months of treatment

Method of measurement

Laboratory kit

3

Description

Anti-gliadin antibody (AGA)

Timepoint

At the beginning of the study and after 3 months of treatment

Method of measurement

Laboratory kit

4

Description

Intraepithelial lymphocytes (IEL)

Timepoint

At the beginning of the study and after 3 months of treatment

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: Celiac patients receive 1 Celiac Support capsule (every 6 hours) for 3 months 30 minutes before eating a diet containing gluten.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Dr Vahid Reza Askari

Street address

Mashhad University of Medical Science, Azadi Square

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askariv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayour-Mobarhan

Street address

Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyze Cinema, University Street

City

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9138813944

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+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of medicine, Paradise of University, Vakil-Abad Blvd., Azadi Sq., Mashhad

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

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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