Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 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)
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+98 51 3800 2264
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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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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 Hoveyzeh Cinema, University Street
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

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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