

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Evaluation of the effect of silymarin in patients with inflammatory bowel disease

Protocol summary

Study aim

Determining the effectiveness of silymarin in patients with inflammatory bowel disease

Design

Clinical trial with a control group, parallel groups, double-blind, randomized, phase 3, on 40 patients. The randomization will be done by the random number table method through the website <http://www.graphpad.com/quickcalcs/index.cfm>.

Settings and conduct

This study will be conducted with the aim of determining the efficacy of silymarin in children suffering from inflammatory bowel disease in Akbar Mashhad Hospital. In the intervention group, silymarin tablets (Gol Daru Company) with a dose of 5 mg per kilogram in divided doses three times a day for three months will be used daily, and in the control group, a placebo will be used, similar to the intervention group. Disease symptoms will be evaluated at the beginning and end of the intervention through a questionnaire. This study is double-blind, the patients and those who evaluate the outcome are unaware of the type of drug received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inflammatory bowel disease
Exclusion criteria: The patient's unwillingness to visit the gastroenterology clinic regularly for regular examinations and check-ups

Intervention groups

Intervention group: Silymarin tablets (Gol Daru Company) with a dose of 5 mg/kg in divided doses three times a day for three months on a daily basis. Control group: Three times a day placebo for three months on a daily basis

Main outcome variables

The main outcome variable will be inflammatory bowel disease symptoms.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101107005123N3**

Registration date: **2023-02-18, 1401/11/29**

Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**

Update count: **0**

Registration date

2023-02-18, 1401/11/29

Registrant information

Name

Hamidreza Kianifar

Name of organization / entity

Mashahd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2469

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kianifarhr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of silymarin in patients with inflammatory bowel disease

Public title

Effect of silymarin in inflammatory bowel disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inflammatory bowel disease

Exclusion criteria:

The patient's unwillingness to visit the gastroenterology clinic regularly for regular examinations and check-ups

Presence of any other comorbidities

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups receiving silymarin tablets and placebo. Random numbers table is used for randomization. In order to use random numbers table, it will be determined first to read the numbers in the table, then the numbers are considered for different groups. We put our hands on one of the numbers and move in one of the predetermined directions and assign the numbers to the desired groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in the intervention group will use silymarin tablets and the control group will use placebo, similar to the intervention group. Patients and doctors who evaluate the outcome will be unaware of the type of drug received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

34591375

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.590

Health conditions studied

1

Description of health condition studied

Inflammatory Bowel Disease

ICD-10 code

K50-K52

ICD-10 code description

Noninfective inflammatory bowel disease

Primary outcomes

1

Description

Clinical Symptoms

Timepoint

Before the start of the study, one month and three months after the start of the intervention

Method of measurement

Questionnaire including abdominal pain, frequency of defecation, mobility and endoscopy findings

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Silymarin tablets (Gol Daro Company) with a dose of 5 mg/kg in divided doses three times a day for three months on a daily basis

Category

Treatment - Drugs

2

Description

Control group: Three times a day placebo for three months on a daily basis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Fatemeh Amani

Street address

Akbar Hospital, Kaveh Blvd, Mashhad

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fatemehamaanii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayouri Mobarhan

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Vice chancellor for research, Mashhad University of
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vcresearch@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

Mashhad University of Medical Sciences

Position

Fellows in Training

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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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