Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Daro 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
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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 Medical Sciences, Daneshgah Ave, Mashhad
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34591375
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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