

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of Nanomicelle curcumin compared to placebo on nutritional and paraclinical findings in children with Crohn's diseases: a triple-blind randomized controlled clinical trial.

Protocol summary

Study aim

Determining and comparing the effect of nanomicelle curcumin supplementation on changes in weight and height and body mass index, body composition, inflammatory biomarkers (based on interleukin 10 and CRP levels) and quality of life of children with Crohn's disease

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 60 patients using web-based randomization.

Settings and conduct

Sixty patients will be selected based on the inclusion criteria from the patients with Crohn's disease referred to Dr. Hamidreza Kayanifar Gastroenterology Clinic in Mashhad, Iran. The participants, evaluators and researchers are unaware of the allocation of the study groups. Supplements and placebos are similar in shape and size. After signing the informed consent, a third party who is blinded to the study will deliver the random allocation sequence and according to this sequence the supplements will be offered to the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 8 to 18 years with Crohn's disease; mild to moderate severity of the disease based on the Crohn's Disease Activity Index (CDAI) criteria; interested in participating in the project and willing to follow the study protocol; providing written informed consent. Exclusion criteria : pregnancy and breastfeeding; using anticoagulants such as warfarin or antiplatelet drugs

Intervention groups

Intervention group: they will receive a weight gain diet along with two nanomicelle curcumin 40-mg supplements; produced by Nanosina; twice a day for 12 weeks. Control group: they will receive the same weight gain diet and placebo supplements twice a day for 12

weeks.

Main outcome variables

Body weight, interleukin 10, albumin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231029059889N1**

Registration date: **2023-12-07, 1402/09/16**

Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**

Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Mehrara Hashempour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-26, 1402/10/05

Expected recruitment end date

2024-03-14, 1402/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Nanomicelle curcumin compared to placebo on nutritional and paraclinical findings in children with Crohn's diseases: a triple-blind randomized controlled clinical trial.

Public title

The effect of nanomicelle curcumin in children with Crohn's disease

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 8 to 18 years old with Crohn's disease Mild to moderate disease severity based on Crohn's Disease Activity Index (CDAI) Interested in participating in the project and willing to follow the study protocol Informed consent has been obtained from the patients

Exclusion criteria:

Using anticoagulants such as warfarin or antiplatelet
Pregnancy and breastfeeding

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description of each method: block; Randomization Unit: Individual; Randomization tool: Sealed envelope, block randomization is done in order to balance the number of samples allocated to each of the study groups. For this purpose, online randomization (<https://www.sealedenvelope.com>) is used. The number and characteristics of the participants are entered in the specified location and people are randomly assigned to one of the intervention and placebo groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this triple-blind study, the participants, the main researcher, the doctor, the supervisors, the people responsible for collecting the data, the people who evaluate the outcome and also the data analyst,

compared to the fact that each person participating in the study in the main intervention group (receiving nanomicelle curcumin supplement) or placebo (without nanomicelle curcumin) are unknown. For blinding, curcumin and placebo nanomicelle capsules will be similar in appearance, packaging and labeling. The packaging and coding process of the capsules will be done by the manufacturer (Nano Sina).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine-
Mashhad University of Medical Sciences

Street address

Nutrition Department, School of Medicine, East door
of Ferdowsi University, Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2023-11-14, 1402/08/23

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.383

Health conditions studied**1****Description of health condition studied**

Children's Crohn's disease

ICD-10 code

K50

ICD-10 code description

Crohn's disease [regional enteritis]

Primary outcomes**1****Description**

Body weight

Timepoint

At the beginning of the study (before the start of the intervention) and 4, 8 and 12 weeks after the start of the supplement consumption

Method of measurement

Scales

2

Description

height

Timepoint

At the beginning of the study (before the start of the intervention) and 4, 8 and 12 weeks after the start of the supplement consumption

Method of measurement

tape measure

3

Description

Serum albumin

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the supplement consumption

Method of measurement

Biochemical analysis of blood sample

4

Description

Body mass index

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the supplement

Method of measurement

Formula (weight/height squared)

Secondary outcomes

1

Description

inflammation status (C-reactive protein)

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the supplement

Method of measurement

Biochemical analysis of blood sample

2

Description

oxidative stress status (Interleukin 10)

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the supplement

Method of measurement

ELISA

3

Description

Body composition (fat mass, fat-free mass, lean body

mass, skeletal muscle index, total body water content, basal metabolic rate)

Timepoint

At the beginning of the study (before the start of the intervention) and 4, 8 and 12 weeks after the start of the supplement

Method of measurement

Bioelectric Impedance Analysis (BIA) device

4

Description

Dietary intake

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the supplement

Method of measurement

3-day 24-hour recall

5

Description

Quality of Life

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the supplement

Method of measurement

Quality of life questionnaire for Crohn's patients

Intervention groups

1

Description

Intervention group: weight gain diet (500 kcal more than daily requirement) and two nanomicelle curcumin supplements (containing 40 mg of nanomicelle curcumin manufactured by Nanosina) are prescribed to the participants for 12 weeks.

Category

Treatment - Other

2

Description

Control group: receiving weight gain diet (500 kcal more than daily requirement) and placebo (the same amount and form of nanomicelle curcumin supplements manufactured by Nanosina Company), prescribed twice a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Clinic of Akbar Children's Hospital

Full name of responsible person

Dr. Hamidreza Kianifar

Street address

Akbar Children hospital; Zakaria Land; Namaz Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Taskheti

Street address

Research and Technology Deputy, Mashhad
University of Medical Sciences, Daneshgah Avenue

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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

Mehrara Hashempour

Position

Master student of medical sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Saeedeh Talebi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mehrara Hashempour

Position

Master student of medical sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Nutrition Department, School of Medicine, East door of Ferdowsi University, Azadi Sq.

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Individually nonidentifiable data of participants will be shared in this study. also, the protocol, results, and statistical analysis of the study will be published in the relevant articles.

When the data will become available and for how long

Access to data begins 6 months after publication of results.

To whom data/document is available

The unidentifiable personal data of the participants will be made available to other researchers at academic institutions.

Under which criteria data/document could be used

The unidentifiable personal data of the participants can only be used for research.

From where data/document is obtainable

Individually nonidentifiable information of participants can be obtained by sending an email to Dr. Saeedeh Talebi (talebis@mums.ac.ir)

What processes are involved for a request to access data/document

Other researchers in academic institutions can send their requests by email to Dr. Saeedeh Talebi. The data will be sent to them after consulting and approving the research team.

Comments