Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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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) and12 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) and12 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) and12 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) and12 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) and12 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
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Full name of responsible person
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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
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Person responsible for updating data

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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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Hashempourm4012@mums.ac.ir

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