Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Evaluation of the Efficacy of Nanomicelle Curcumin Formulation in Children with Ulcerative Colitis (UC)

Protocol summary

Study aim
Evaluation of the Efficacy of Nanomicelle Curcumin Formulation in Children with Ulcerative Colitis (UC)

Design
A clinical trial with a control group, with parallel groups, three-way blind, randomized, phase 2 on 40 patients, www.randomization.com was used for randomization.

Settings and conduct
This study includes intervention and control groups. In addition to receiving standard treatment(based on the severity of the disease and according to the instructions of ESPGHAN Guideline) (sulfasalazine), patients in the control group will be given a volume equivalent of placebo syrup and in the intervention group curcumin syrup at a dose of 40 mg/d for 2 months. The study is performed in Akbar Children's Hospital in Mashhad The study is three-way blind: the subjects, evaluators, analysts, sample allocators to the groups.

Participants/Inclusion and exclusion criteria
Entry conditions: All children aged 6-18 years referred to Akbar Hospital Gastroenterology Clinic, who have been diagnosed with mild to moderate severity according to ESPGHAN Guideline criteria, obtain informed consent of the patient / patient's parents. Non-entry conditions: child with a history of underlying disease including heart, kidney, liver, biliary, gastrointestinal diseases (any disease Gastrointestinal other than UC) Concomitant use of anticoagulants such as warfarin or antiplatelet drugs by the patient, diabetics

Intervention groups
In addition to receiving standard treatment (sulfasalazine), patients in the control group will be given a volume equivalent of placebo syrup and in the intervention group curcumin syrup at a dose of 40 mg/d for 2 months.

Main outcome variables
Check the Pediatric Ulcerative Colitis Activity Index, the Simple Clinical Colitis Activity Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191221045837N2**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **prospective**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**

Registration date
2020-10-16, 1399/07/25

Registrant information

Name
Zinat Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3180 1584

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heidarizn@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the Efficacy of Nanomicelle Curcumin Formulation in Children with Ulcerative Colitis (UC)

Public title

Effect of Nanomicelle Curcumin in Ulcerative Colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 6-18 years old who , according to the ESPHAN Guideline , have mild to moderate active Ulcerative Colitis Obtain informed consent from the patient/ patient's parents

Exclusion criteria:

Child with a history of underlying disease including heart, kidney, liver, biliary, gastrointestinal diseases (any gastrointestinal disease other than UC) simultaneously Taking anticoagulants such as warfarin or antiplatelet drugs by the patient Diabetic patients

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization method: Block randomization:This method is used to prevent significant imbalances in the number of participants assigned to each group. Block randomization ensures that no significant imbalance is established between groups at any time during randomization Randomization unit: individual Randomization tool: https://www.sealedenvelope.com/ How to make a random sequence: For this method, the size of each block must first be specified (for example, a quadruple block). Then write a list of blocks and assign numbers to them (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then select random numbers between one and 6 (Eg 1 4 5, etc.) and finally specify the treatment allocation list based on previous random numbers (... AABB-BBAA-BABA-) In this study, we use 4 blocks and the site https://www.sealedenvelope.com randomizes and numbers the blocks. Allocation Concealment Method: Sealed Envelopes

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is three-way blind in which the subjects, evaluators, analysts, sample allocators will be unaware of the intervention and control groups. Drugs and placebo, numbered 1-40, will be identified and distinguished by the drug manufacturing company, which belong to the drug or placebo group based on a random list prepared from www.sealedenvelope.com. The physician, patients, and analyst will remain unaware of the type of formulation until the work is completed. Patients receive one of the medicine containers, number 1-40, from the pharmacy student, respectively. The list will be decrypted when completed.

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

Razavi Khorasan Province, Mashhad, Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.MUMS.REC.1398.253

Health conditions studied

1

Description of health condition studied

Children with Ulcerative Colitis (UC)

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

the Pediatric Ulcerative Colitis Activity Index (PUCAI)

Timepoint

Assess the severity of the disease at baseline, at the end of the first month and at the end of the second month of treatment

Method of measurement

Stool exam and PUCAI questionnaires

2

Description
the Simple Clinical Colitis Activity Index (CSCCAI)
Timepoint
Assess the severity of the disease at baseline, at the end of the first month and at the end of the second month of treatment
Method of measurement
Stool exam and CSCCAI questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Control group : In addition to the standard treatment (sulfasalazine), a volume equivalent of placebo syrup will be given daily for two months.
Category
Placebo

2

Description
Intervention group: In addition to standard treatment (sulfasalazine), curcumin syrup at a dose of 40 mg daily will be prescribed for two months. Due to the lipophilic nature of curcumin, the oral absorption of curcumin in common oral forms (powder, capsules and tablets) is very low. However, in Sina-Curcumin (manufactured by Exir Nano Sina Company), all curcumin is trapped in the hydrophobic part of curcumin nanoparticles. These spherical nano-micels have a particle size of about 10 nanometers and increase the solubility of curcumin in water. After oral administration, soft gel capsules containing curcumin nano-micels are dispersed in the acidic environment of the open stomach in less than 15 minutes. These nano-micels are stable in the acidic environment of the stomach for at least 6 hours and do not die and reach the small intestine intact. Once in the small intestine, the nano-micels facilitate the transfer of curcumin from the intact water layer on the surface of intestinal epithelial cells, which is a barrier to the absorption of fat-soluble compounds and increase the absorption of curcumin orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar pediatric hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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Zinat Heidari
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the end of the study and data collection and data transfer to SPSS software, all patient data can be shared after unidentified individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic, scientific and industrial institutes
Under which criteria data/document could be used
No one is allowed to use the documents except the principal investigator.
From where data/document is obtainable
Send an email to Dr. Zeinat Heydari. heidarizn@mums.ac.ir
What processes are involved for a request to access

data/document

Send an email to Dr. Zeinat Heydari.

heidarizn@mums.ac.ir

Comments