Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the Efficacy of Nanomicelle Curcumin Formulation in Children with Juvenile Idiopathic Arthritis(JIA)

Protocol summary

Study aim
Evaluation of the Efficacy of Nanomicelle Curcumin Formulation in Children with Juvenile Idiopathic Arthritis(JIA)

Design
A clinical trial with a control group, with parallel groups, triple blind, randomized, phase 3 on 40 patients, www.randomization.com was used for randomization.

Settings and conduct
In this study In addition to receiving standard treatment(based on the severity of the disease and according to the instructions of ACR Guidline1) (methotrexate), 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: 1- All children between 6 and 16 years old referred to Akbar hospital Rheumatology subspecialty clinic who diagnosed suffering JIA according to ACR Guidline1 2- Obtain patient/patient's parents informed consent Non-entry conditions: 1- Children under 6 years old and or teenagers older than 18 years old 2- Child with a history of underlying diseases including heart, kidney, liver, bile, digestive and or reumatoid (any kind of reumatoid diseases except JIA) diseases simultaneous 3- Consuming anticoagulant medicines like warfarin or anti-platelet medicines by patient 4- Diabetic patients

Intervention groups
.. In all patients, illness severity will be evaluated(based on ACR-Pedi30 Score) at the beginning, after 1 and 3 months from the start of treatment. at the end of research, illness severity will be statistically compared between intervention and control group and also difference of responses will be evaluated based on gender.

Main outcome variables
check JIA Activity Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191221045837N1**
Registration date: **2020-09-28, 1399/07/07**
Registration timing: **prospective**

Last update: **2020-09-28, 1399/07/07**
Update count: **0**

Registration date
2020-09-28, 1399/07/07

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 Juvenile Idiopathic Arthritis(JIA)

Public title
Effect of Nano-Curcumin in Juvenile Idiopathic Arthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All children between 6 and 16 years old referring to Akbar hospital Rheumatology subspecialty clinic who diagnosed suffering JIA according to ACR Guidline1 Obtain patient/patient's parents informed consent

Exclusion criteria:
Children under 6 years old and or teenagers older than 16 years old Child with a history of underlying diseases including heart, kidney, liver, bile, digestive and or reumatoid (any kind of reumatoid diseases except JIA) diseases simultaneous Consuming anticoagulant medicines like warfarin or anti-platelet medicines by patient Diabetic patients

Age
From **6 years** old to **16 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: www.randomization.com website 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 3 6, etc.) and finally specify the treatment allocation list based on previous random numbers (... AABB-ABBA-BAAB-) Allocation Concealment Method: Sealed Envelopes

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study is three-way blind in which the subjects, evaluators, analyzer, sample allocators will be unaware of the intervention and control groups.

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
2019-12-07, 1398/09/16

Ethics committee reference number
IR.MUMS.REC.1398.249

Health conditions studied

1

Description of health condition studied
Children with Juvenile Idiopathic Arthritis(JIA)

ICD-10 code
M08

ICD-10 code description
Juvenile arthritis

Primary outcomes

1

Description
In all patients, the severity of JIA disease will be assessed and recorded at baseline, at the end of the first month and at the end of the third month of treatment using the ACR-Pedi30 Score. The main factors examined in the ACR-Pedi30 Score are: 1- Physician evaluation of the disease activity (PhGA) 2- Evaluation of the patient or parents of the child from their child's health 3- Evaluation of joint function 4- Number of joints involved 5- Number of joints with limitations in Range of motion (ROM) 6- ESR measurement.

Timepoint
At baseline, at the end of the first month and the end of the third month of treatment
Method of measurement
1- Physician evaluation of the disease activity (PhGA) 2- Evaluation of the patient or parents of the child from their child's health 3- Evaluation of joint function 4- Number of joints involved 5- Number of joints with limitations in Range of motion (ROM) 6- ESR measurement.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, patients with JIA will receive standard JIA treatment (according to the ACR 2019 Guideline) along with 40 mg daily curcumin syrup for 3 months.
Category
Treatment - Drugs

2

Description
Control group: In the control group, patients will receive standard treatment of JIA and the volume equivalent of placebo syrup daily for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar pediatric hospital
Full name of responsible person
Zinat Heidari
Street address
Akbar pediatric hospital, Shahid Kaveh Boulevard, Mashhad, Khorasan Razavi.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mohsen Tafaghodi
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https://v-research.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
Zinat Heidari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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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