Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Efficacy of Ginger Supplementation with Pellet Formulation in Children with Juvenile Idiopathic Arthritis(JIA)

Protocol summary

Study aim
Evaluation of the efficacy of ginger supplementation on the severity of JIA according to the ACR-Pedi30 Score

Design
A placebo-controlled, randomized, double-blinded, phase 2-3 clinical trial on 50 patients with JIA. Block randomization was used for randomization.

Settings and conduct
The study will be conducted as a double-blind clinical trial in experimental and control groups. Fifty children (aged 6-16 years) referred to rheumatology clinic of Akbar hospital, who have been diagnosed with JIA according to the ACR guideline, will be included in the study. Then, they will be randomly assigned to experimental or control groups.

Participants/Inclusion and exclusion criteria
inclusion criteria: - Children (aged 6-16 years) referred to rheumatology clinic of Akbar hospital, who have been diagnosed with JIA according to the ACR guideline. - Obtaining informed consent of the patient / patient's parents exclusion criteria: -A child with a history of underlying disease, including cardiac, renal, hepatic, biliary, gastrointestinal, or rheumatic disorders (other than JIA), at the time of enrollment -Use of anticoagulants (such as warfarin) or antiplatelet agents - Diabetic patients

Intervention groups
Intervention group: included patients will receive standard treatment of JIA and ginger pellets (containing hydro-alcoholic ginger extract equivalent to 250 mg of ginger rhizome powder, standardized based on Shogaol and phenolic acids contents) twice a day for 3 months. Control group: Included patients will receive standard treatment of JIA and placebo pellets (twice daily) for 3 months.

Main outcome variables
Disease severity will be assessed at baseline, end of the first month, and end of the third month of treatment using the ACR-Pedi30 Score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191221045837N4**
Registration date: **2021-12-08, 1400/09/17**
Registration timing: **prospective**

Last update: **2021-12-08, 1400/09/17**
Update count: **0**

Registration date
2021-12-08, 1400/09/17

Registrant information

Name
Zinat Heidari

Name of organization / entity

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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
2022-01-05, 1400/10/15

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the Efficacy of Ginger Supplementation with Pellet Formulation in Children with Juvenile Idiopathic Arthritis(JIA)

Public title

Evaluation of the Efficacy of Ginger Supplementation with Pellet Formulation in Children with Juvenile Idiopathic Arthritis(JIA)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children (aged 6-16 years) referred to rheumatology clinic of Akbar hospital, who have been diagnosed with JIA according to the ACR Guideline. Obtaining informed consent of the patient / patient's parents

Exclusion criteria:

A child with a history of underlying disease, including cardiac, renal, hepatic, biliary, gastrointestinal, or rheumatic disorders (other than JIA), at the time of enrollment Use of anticoagulants (such as warfarin) or antiplatelet agents Diabetic patients

Age

From **6 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization Randomization tool: https://www.sealedenvelope.com/ How to make a random sequence: To perform this method, the number of intervention groups (two groups A and B), the volume of each block (4 in each block) and sample size (50 patients) were entered into the website. Then, the site creates a randomization list of 13 blocks, each contains 4 patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, evaluators, data analysts, and technicians are blinded.

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

Central department of Mashhad University of Medical Sciences, next to Alton Tower, Daneshgah Street, Mashhad, Khorasan Razavi Province, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.MUMS.REC.1399.460

Health conditions studied

1

Description of health condition studied

juvenile idiopathic arthritis (JIA)

ICD-10 code

M08

ICD-10 code description

Juvenile arthritis

Primary outcomes

1

Description

Disease severity will be assessed at baseline, end of the first month, and end of the third month of treatment using the ACR-Pedi30 Score. The core criteria for ACR Pedi 30 score are: 1) physician global assessment of disease activity (PhGA); 2) parent/patient global assessment of overall well-being; 3) functional ability; 4) number of joints with active arthritis; 5) number of joints with limited range of motion; and 6) ESR.

Timepoint

At baseline, end of the first month, and end of the third month of treatment

Method of measurement

1) physician global assessment of disease activity (PhGA); 2) parent/patient global assessment of overall well-being; 3) functional ability; 4) number of joints with active arthritis; 5) number of joints with limited range of motion; and 6) ESR.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: included patients will receive standard treatment of JIA and ginger pellets (containing hydro-alcoholic ginger extract equivalent to 250 mg of ginger rhizome powder, standardized based on Shogaol and phenolic acids contents) twice a day for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Included patients will receive standard treatment of JIA and placebo pellets (twice daily) for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar pediatric hospital
Full name of responsible person
Zinat Heidari
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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
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Web page address
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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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
At the end of study, all medical records of patients will be shared.

When the data will become available and for how long
The access period starts 6 months after the publication.

To whom data/document is available
Researchers affiliated to academic, scientific and industrial institutes

Under which criteria data/document could be used
No one is allowed to use the documents except the principal researcher.

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