

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the Effects of Zingiber officinale plate on Growth Pains in Pediatrics

Protocol summary

Study aim

The aim of this study is to investigate the effect of taking ginger tablets on reducing growing pains in children.

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 50 patients. Random Allocation Software was used for randomization.

Settings and conduct

Children with confirmed growing pains (Akbar Hospital, Mashhad) after excluding organic causes will be included. Treatment groups will be concealed using coded packets (Sealed Envelope) dispensed randomly to blind patients, creating intervention/control groups. Pain (VAS) and growing pains symptoms (checklist: duration, sequence, sleep disturbance) will be assessed at baseline and after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study: Age 3 to 12 years Clinical diagnosis of growth pain by a specialist physician after ruling out organic causes of the pain. Patient and guardian consent to the study and completion of an informed consent form by the patient's legal guardian. Exclusion criteria for the study: Having underlying diseases that may cause similar pain. Regular use of anti-inflammatory or analgesic medications. Known allergy to ginger.

Intervention groups

Patients in the intervention group will receive tablets containing ginger extract (hydroalcoholic extract equivalent to 250 mg of ginger rhizome powder, standardized based on Shogaol and phenolic acids content) BID for 3 months.

Main outcome variables

Visual Analogue Scale (VAS) of pain and tool for children's growing pains and checklist of symptoms associated with pain including duration of pain, sequence of pains, sequence of awakening from sleep or sleep disturbance due to growing pains

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250203064631N1**

Registration date: **2025-06-02, 1404/03/12**

Registration timing: **prospective**

Last update: **2025-06-02, 1404/03/12**

Update count: **0**

Registration date

2025-06-02, 1404/03/12

Registrant information

Name

Mahdieh Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8883

Email address

alizadehm4022@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-05, 1404/03/15

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effects of Zingiber officinale plate on Growth Pains in Pediatrics

Public title

Investigating the Effects of Zingiber officinale plate on Growth Pains in Pediatrics

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 3 to 12 years Clinical diagnosis of growing pains by a specialist physician after ruling out organic causes of pain. Patient and guardian consent to the study and completion of the informed consent form by the patient's legal guardian.

Exclusion criteria:

Having underlying diseases that may cause similar pain. Regular use of anti-inflammatory or analgesic medications. Known allergy to ginger.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

3

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

In this study, the block method will be used to generate the sequence of random allocation of individuals to the study groups. The sequence of random allocation of individuals will be done using Random Allocation Software and a block size of 4. In this study, 6 blocks of 4 will be our guide in this study. The block randomization method from the specified blocks should be selected each time random numbers are generated.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To conceal the allocation, before assigning the individual, using sealed opaque envelopes, the random sequences created are recorded on a card and the cards are placed inside the envelopes in order. In order to maintain the random sequence, the envelopes are numbered in the same order on the outside. Finally, the envelopes are taped shut and placed in a box in order. At the start of the participants' arrival, based on the order of the eligible participants entering the study, and after ensuring that the individual has entered the study, one of the envelopes is opened in order and the assigned group of that participant is revealed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the Faculty of Medicine, Mashhad University of Medical Sciences

Street address

Central Organization of Mashhad University of Medical Sciences, Knowledge and Health City, between Shahid Al Shahidi Square and Shahid Javan Square, end of Shahid Fakuri Boulevard, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2025-04-08, 1404/01/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.030

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

Growing pains

ICD-10 code

R29.8

ICD-10 code description

Other and unspecified symptoms and signs involving the nervous and musculoskeletal systems

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

Symptoms associated with pain

Timepoint

At the beginning of the study and after three months of receiving the drug

Method of measurement

The Visual Analogue Scale (VAS) of pain and the Tool for Children's Growing Pains complement the checklist of symptoms associated with pain, including duration of pain, sequence of pains, sequence of awakenings from sleep or sleep disturbance due to growing pains.

2

Description

Duration of pain

Timepoint

At the beginning of the study and after three months of receiving the drug

Method of measurement

The Visual Analogue Scale (VAS) of pain and the Tool for Children's Growing Pains complement the checklist of symptoms associated with pain, including duration of pain, sequence of pains, sequence of awakenings from sleep or sleep disturbance due to growing pains.

3

Description

Sequence of pains

Timepoint

At the beginning of the study and after three months of receiving the drug

Method of measurement

The Visual Analogue Scale (VAS) of pain and the Tool for Children's Growing Pains complement the checklist of symptoms associated with pain, including duration of pain, sequence of pains, sequence of awakenings from sleep or sleep disturbance due to growing pains.

4

Description

Wake-up sequence

Timepoint

At the beginning of the study and after three months of receiving the drug

Method of measurement

The Visual Analogue Scale (VAS) of pain and the Tool for Children's Growing Pains complement the checklist of symptoms associated with pain, including duration of pain, sequence of pains, sequence of awakenings from sleep or sleep disturbance due to growing pains.

5

Description

Possibility of falling asleep due to growing pains

Timepoint

At the beginning of the study and after three months of receiving the drug

Method of measurement

The Visual Analogue Scale (VAS) of pain and the Tool for Children's Growing Pains complement the checklist of symptoms associated with pain, including duration of pain, sequence of pains, sequence of awakenings from sleep or sleep disturbance due to growing pains.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive tablets containing ginger extract (hydroalcoholic extract equivalent to 250 mg of ginger rhizome powder, standardized based on Shogaol and phenolic acids content) BID for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive placebo tablets (BID), which are similar in appearance to ginger tablets, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Superspecialty Hospital

Full name of responsible person

Abdolreza Malek

Street address

opposite Shahid Kaveh 14, Shahid Kaveh Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Central Organization of Mashhad University of Medical Sciences, Knowledge and Health City, between Shahid Al Shahidi Square and Shahid Javan Square, end of Shahid Fakuri Boulevard, Mashhad

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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

Abdolreza Malek

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Full name of responsible person

Abdolreza Malek

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

Not applicable

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

After the results are published in reputable journals, interested parties can access the article.

When the data will become available and for how long

The period of access to results begins after the completion of the research.

To whom data/document is available

All people interested in the research topic can access the

results.

Under which criteria data/document could be used

After publishing the results in the form of a thesis and article, interested parties who need further explanations can access the authors through the communication channels included in the article and ask their questions. If raw data is needed, approval or disagreement will be announced after the research team reviews it.

From where data/document is obtainable

To receive the documentation, you can refer to the email address of the responsible author.

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

Requests will be responded to within a maximum of one week.

Comments