Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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Position
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Abdolreza Malek

Position
Associate Professor

Latest degree
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Other areas of specialty/work
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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