Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of arginine administration on height growth of Children in lower limit range

Protocol summary

Study aim
Investigating the effect of arginine administration on the linear growth of prepubescent children with low-normal stature over a one-year period at Bu Ali Children's Hospital in Ardabil

Design
A single-blind clinical trial will be conducted at Boali Children's Hospital in Ardabil in 1401 with a sample size of 76 children (38 males, 38 females) above age 5, selected randomly from the medical clinics of the University of Medical Sciences in Ardabil. Their group assignment was determined using identical packets.

Settings and conduct
This randomized controlled trial was conducted at the Bu Ali Children's Hospital in Ardabil. Children were systematically divided into control and treatment groups. The study maintained a double-blind approach where neither the participants nor the investigators were aware of the supplement (arginine or placebo) given to the children.

Participants/Inclusion and exclusion criteria
The study will involve 76 prepubescent children, including 38 boys and 38 girls, who fall under the lower limit of normal height (3rd and 10th percentiles). Inclusion criteria: Prepubescent children who are healthy but fall under the lower limit of normal height.Exclusion criteria: Any individual requiring growth hormone therapy or experiencing severe side effects from arginine will be excluded from the study.

Intervention groups
Control group: Will receive daily Vitamin D supplement at a dosage of 1,000 IU and a placebo capsule resembling the arginine capsule used in the study. Treatment group: Along with a daily Vitamin D supplement at a dosage of 1,000 IU, will also receive 250 mg of arginine per day.

Main outcome variables
Height increment; Weight gain; Rate of linear growth.

General information

Reason for update
Acronym
AHGC
IRCT registration information
IRCT registration number: **IRCT20230603058376N1**
Registration date: **2023-10-07, 1402/07/15**
Registration timing: **prospective**

Last update: **2023-10-07, 1402/07/15**
Update count: **0**
Registration date
2023-10-07, 1402/07/15

Registrant information
Name
Emad Rahiminezhad kisomi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 45 3372 4368
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emad0313.mr@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-11, 1402/07/19
Expected recruitment end date
2024-10-10, 1403/07/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of arginine administration on height growth of Children in lower limit range

Public title
Arginine effect on height growth of children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children in pre-pubertal ages Absence of any underlying diseases Not below the lower normal height limit No indications for growth hormone prescription
Exclusion criteria:
Having reached sexual maturity Presence of underlying diseases such as diabetes, hypothyroidism, or kidney diseases Height below the lower normal limit Past or current use of growth hormone Sensitivity or adverse reactions to Vitamin D or Arginine
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method and Explanation for Each: Simple randomization has been utilized. In this method, each participant is randomly allocated to either the control or intervention group. Unit of Randomization: Individual-level randomization. Stratification Layers: Gender stratification has been implemented, ensuring that for every male child selected, a female child is included, and vice versa. Randomization Tool: Similar packets indicating Group A (control) or Group B (intervention). Procedure for Creating a Random Sequence: The sample size has been determined using the G-POWER software. Once participants are selected, a random sequence for entry into groups is established. Explanation on Allocation Concealment: Participants are assigned to various groups using indistinguishable packets, unaware of their contents. Consequently, participants remain blinded to their group assignments.
Blinding (investigator's opinion)
Single blinded
Blinding description
To keep participants unaware of which group they belong to, similar packets will be prepared. Participants will randomly pick one of these packets, which will indicate whether they are in Group A (control) or Group B (intervention), but they will not be told the type of intervention being applied in their group. This ensures a single-blind study design.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences
Street address
Ardabil university of medcal sciences, Daneshgah st., Ardabil
City
Ardabil
Province
Ardabil
Postal code
8599156189
Approval date
2023-08-26, 1402/06/04
Ethics committee reference number
IR.ARUMS.REC.1402.129

Health conditions studied

1

Description of health condition studied
Short stature
ICD-10 code
R62.52
ICD-10 code description
Short stature (child)

Primary outcomes

1

Description
Height of a child
Timepoint
12 months with 3 month interval
Method of measurement
Height measuring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vitamin D 1000 IU daily + Argenine

250mg daily

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali hospital

Full name of responsible person

Simin zare

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

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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

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Simin zare

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Resident

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Medical doctor

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Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Privacy

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
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
Periodical report

When the data will become available and for how long
After publishing the results

To whom data/document is available
Medical researchers

Under which criteria data/document could be used
To access non-personally identifiable data or documents, applicants must commit to preserving data confidentiality. The use of these data is permitted solely for non-invasive analyses intended for scientific research. Additionally, access is granted only after a thorough review by a specialized committee and for a restricted duration. Requests should specify the purpose and the required duration for access.

From where data/document is obtainable
To obtain the data/documentation, applicants can contact the responsible executor. The preferred method of contact is via email.

What processes are involved for a request to access data/document
Applicants must provide a comprehensive introduction of themselves and clearly state their objectives in the submitted email. If deemed appropriate by the administrators, the data will be made available to the requester.

Comments