Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of high-calorie-high-protein diet enriched with arginine food resource with calcium supplementation on anthropometric indices and growth plate status of 4-8 years old children with developmental disorders

Protocol summary

Study aim
Determining effect of high-protein-high-calorie diet enriched with arginine food sources along with calcium supplement on anthropometric indicators and growth plate status of 4-8 year old children with growth disorder

Design
This study is a single-blind clinical trial with a parallel design and an allocation ratio of 1:1:1.

Settings and conduct
This study will be conducted in a period of 12 weeks on 99 children aged 4-8 years with developmental disabilities in Mohammad Kermanshahi Hospital. After explaining the objectives of the research and obtaining informed consent, the subjects will be evaluated for their growth plate status and anthropometric indicators.The condition of the growth plate will be measured using radiography of the wrist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 4-8 years, BMI less than 3 percentile of BMI chart for age or height less than 3 percentile of WHO height chart for age. Exclusion criteria: being under special diets in the last 6 months, suffering from endocrine, liver, kidney, thyroid, celiac disease and taking steroid or hormonal drugs.

Intervention groups
The first intervention group: children who are underweight (less than the 3rd percentile of the WHO BMI chart for age) and short (less than the 3rd percentile of the WHO height chart for age) under a high-protein-high-calorie diet for 12 weeks. Second intervention group: underweight and short children under a high-protein-high-calorie diet enriched with arginine food sources including peanuts, walnuts, soybeans (8 grams each), at night and before bed and calcium supplements (in the amount of 1 tablespoon daily with lunch). Control group: children with normal height and weight.

Main outcome variables
Growth plate status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181111041611N5**
Registration date: **2022-10-06, 1401/07/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-06, 1401/07/14**
Update count: **0**

Registration date
2022-10-06, 1401/07/14

Registrant information

Name
Mehnoosh Samadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3710 2009

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mehnoosh_samadi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of high-calorie-high-protein diet enriched with arginine food resource with calcium supplementation on anthropometric indices and growth plate status of 4-8 years old children with developmental disorders

Public title

Evaluation of high-protein-high-calorie diet on the state of children's growth plate

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A BMI below the 3rd percentile of the WHO BMI chart for age Height placement below the 3rd percentile of the WHO height-for-age chart

Exclusion criteria:

Lack of endocrine disease

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: stratified randomization. The participants of this study are selected from among children with developmental delay referred to pediatric endocrinologists, after obtaining the necessary criteria. The person in charge of the project will register the samples by attending the endocrinology and pediatric office, and then according to the random sequence determined by the statistical consultant, the samples will be allocated to the intervention groups. In this study, stratified randomization will be used to ensure the balance of the characteristics of the participants in each group in terms of basic characteristics, such as growth plate status and gender. Stratified randomization ensures that the number of participants receiving each intervention will be perfectly balanced in each stratum. In this method, the randomization of the first layer will be based on gender and the next layer will be based on the state of the growth plate. Then, to hide the randomization, the allocation of the participants will be done by a computer or a random number list of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because the intervention is in the form of providing diet, in this study, the participants and nutritionists are aware of the assigned arm to the intervention group, but the outcome assessors and data analysts will be blinded to the allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran

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Kermanshah

Postal code

6719851351

Approval date

2022-09-05, 1401/06/14

Ethics committee reference number

IR.KUMS.REC.1401.252

Health conditions studied

1

Description of health condition studied

Growth retardation

ICD-10 code

E64.0

ICD-10 code description

Sequelae of protein-energy malnutrition

Primary outcomes

1

Description

Growth plate status

Timepoint

Before the start of the study, 12 weeks after the start of the intervention

Method of measurement

X-ray of the wrist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1:They will be subjected to a high-protein-high-calorie diet for 12 weeks. In this intervention, the amount of energy needed by each patient will be calculated based on the normal weight and age and the protein content of 18% of the total calories. And at the end, in order to ensure the implementation of the diet, parents are asked to record the food received by the child in the form of a 3-day food record (two regular days and one day off) at the beginning of the study and the 6th week and at the end of the study, and in the counseling sessions which will be formed every week for the purpose of follow-up and provide to the relevant official.

Category

Treatment - Devices

2

Description

Intervention group2:under a high-protein-high-calorie diet enriched with arginine food sources including peanuts, walnuts, soybeans (8 grams each), in the evening meal and before going to bed and calcium supplement (at the rate of 1 tablespoon daily with lunch) for 12 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Karam Ahmadian

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Gomrek Street, Kermanshah, Iran

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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mehnoosh Samadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available