

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of vitamin D on serum level of Insulin-like growth factor 1 in 5-10 years old children with idiopathic short stature

Protocol summary

Study aim

The effect of vitamin D supplementation on IGF-1 levels in children with idiopathic short stature

Design

In the present study, 60 children aged 5 to 10 years with short stature, 30 of whom had vitamin D levels less than 30 ng / dl and the second 30 had normal vitamin D levels, were selected and the first group was treated with vitamin D. In the second group, no intervention is performed. Insulin-like growth factor levels are determined and compared at the beginning and end of the intervention in the two groups.

Settings and conduct

Isfahan Imam Hossein Hospital, children with vitamin D levels less than 29 ng / ml, were treated with 50,000 units of vitamin D supplement per week for 8 weeks. After 3 months of treatment, vitamin D and IGF-1 levels were measured again and the results were recorded along with other patient information in the data collection form.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: idiopathic short stature, age range 5-10 years, low IGF-1 level, vitamin D level less than 29 ng / ml and parental consent to participate in the study.

Intervention groups

Children with vitamin D levels below 29 ng / ml are treated with 50,000 units of vitamin D supplement per week for 8 weeks. Vitamin D is not recommended for children with vitamin D levels above 30 ng / dL. Vitamin D levels and insulin-like growth factor are measured and compared in two groups at the beginning and end of the study.

Main outcome variables

The present study showed that with the elimination of vitamin D deficiency, the level of IGF-1 increases, so it seems that in children with idiopathic short stature, eliminating vitamin D deficiency can be effective in eliminating IGF-1 deficiency.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200622047874N1**

Registration date: **2021-02-15, 1399/11/27**

Registration timing: **prospective**

Last update: **2021-02-15, 1399/11/27**

Update count: **0**

Registration date

2021-02-15, 1399/11/27

Registrant information

Name

marjan zareian jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 6557

Email address

zareian@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D on serum level of Insulin-like growth factor 1 in 5-10 years old children with idiopathic short stature

Public title

Effect of vitamin D on improvement of n 5-10 years old children with idiopathic short structure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Idiopathic short structure Age range 5-10 years Low IGF-1 level Parental consent for interewd to study

Exclusion criteria:

Vitamin D level less than 29 ng / ml

Age

From **5 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients in both groups is done using random allocation software. In the mentioned software, the total number of sample size and the number of groups are entered and the software output includes a list that has randomly distributed the total sample size in two groups according to the number. Patients are distributed in two groups according to the time of referral according to the list.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining permission from the University Medical Ethics Committee, the researcher referred to the endocrinology clinic of Imam Hossein Hospital, found children with inclusion criteria, explained the objectives of the research to the patients' parents, and after obtaining written consent, 5 ml of blood sample. Intravenously will be taken from children to measure 25-hydroxy vitamin D and IGF-1 levels

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan university of medical sciences

Street address

Hezarjareeb

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.MUI.REC.1396.3.283

Health conditions studied

1

Description of health condition studied

Idiopathic Short Structure

ICD-10 code

R62.52

ICD-10 code description

Idiopathic Short Structure

Primary outcomes

1

Description

Idiopathic short structure

Timepoint

Three months

Method of measurement

Vitamin D and IGF-1 levels were measured by blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Children with vitamin D levels less than 29 ng / ml will be treated with 50,000 units of vitamin D supplement per week for 8 weeks. Vitamin D and IGF-1 levels will be measured again 3 months after starting treatment

Category

Treatment - Drugs

2

Description

Control group: In this group, routine care measures are performed and no intervention is performed. Only vitamin D levels and insulin-like growth factor were measured at the beginning and end of the study, and the results were compared with the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person

Elham Hashemi

Street address

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8174673461

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+98 31 3620 2020

Email

hashemielham@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Research faculty, Isfahan University of Medical Sciences. Hezarjareeb,

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Elham Hashemi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Esfahan University of Medical Sciences

Full name of responsible person

Elham Hashemi

Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

Full name of responsible person

Elham Hashemi

Position

Consultant

Latest degree

Specialist

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

The plan belongs to a government agency and cannot be shared.

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