

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

To study the effect of oral calcium and vitamin D3 supplementation on bone mineral density in children with acute lymphoblastic leukemia

Protocol summary

Study aim

Determining the effect of Vitamin D and oral Calcium on bone density in children with leukemia.

Design

This study is a triple blind controlled clinical trial with parallel group design. The randomization method will be simple randomization. Each group includes 66 patients. In the intervention group vitamin D and calcium supplements are given in addition to common treatments.

Settings and conduct

This study will be conducted at Amir Kabir Hospital in Arak. For all patients with acute lymphoblastic leukemia (ALL), bone mineral density (BMD) and serum level of ALKP, P, Ca, 25OH D3 will be measured at baseline. Then the patients will randomly enter into two groups. In intervention group, patients receive calcium, 30-40 mg/kg per day and vitamin D, 400 units per day in addition to Chemotherapy and patients in the other group only receive chemotherapy. Six months after the start of the treatment, BMD and serum markers will be remeasured. This study is triple blind and clinical care providers, Researchers and Data analyzer will be kept blind to the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with acute lymphoblastic leukemia; being at the age of over 5 years old. Exclusion criteria: Patients with no compliance with the supplements; Patients with no satisfaction to continue the study; no compliance in the use of enteric supplements; Patients who don't have bone marrow densitometry.

Intervention groups

Patients are assigned randomly into two groups, and in the intervention group in addition to chemotherapy drugs, we add calcium and vitamin D supplements.

Main outcome variables

Bone mineral density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150119020715N7**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Aziz Eghbali

Name of organization / entity

دانشگاه علوم پزشکی اراک

Country

Iran (Islamic Republic of)

Phone

+98 86 3465 5314

Email address

dr.eghbali@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-04, 1397/02/14

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To study the effect of oral calcium and vitamin D3 supplementation on bone mineral density in children with acute lymphoblastic leukemia

Public title

to study the effect of calcium and vitamin D supplementation in children with leukemia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All of the children with acute lymphoblastic leukemia above 5 years old

Exclusion criteria:

Patients with no compliance with using supplements
Patients with no satisfaction to continue the study
No compliance with enteric use of supplements
Not doing bone marrow densitometry

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization.
Randomization tools: Random Numbers table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Care providers will be blind to the type of medication
The data analyzer is also blind to the grouping. The Data and Safety Monitoring Board is also unaware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

38481769411

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.ARAKMU.REC.1396.299

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

leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

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

bone mineral density

Timepoint

in the beginning of the study (before the intervention) and 6 months after the intervention

Method of measurement

Bone Mineral Densitometry

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to chemotherapy drugs, patients receive 30-40 mg/kg calcium and 400 units per day of vitamin D.

Category

Treatment - Drugs

2**Description**

Control group: For the control group members routine care is done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Aziz Eghbali

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3819693345, Amir Kabir Hospital, Basij Square, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad arjomandzadegan

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Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak, Iran

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Aziz Eghbali

Position

Faculty, Pediatrics Oncologist

Latest degree

Subspecialist

Other areas of specialty/work**Street address**

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Contact

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Full name of responsible person

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Position

Faculty, Pediatrics Oncologist

Latest degree

Subspecialist

Other areas of specialty/work

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Contact

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Web page address

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

Participants information will remain confidential

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

Undecided - It is not yet known if there will be 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

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