Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Evaluation of The effects of Alendronates on Osteopenia in Children with Acute Leukemia

Protocol summary

Study aim
Evaluation and comparison of the degree of change in the severity of osteopenia after six months in patients before and after taking alendronate

Design
A single arm, non-blind, nonrandomized, phase 2 clinical trial on 30 patients.

Settings and conduct
30 patients with acute leukemia referred to Tabriz Children's Educational and Medical Center are randomly selected. Alendronate will be given for 6 months. They will receive daily calcium syrup and vitamin D 50,000 IU N tablets every two weeks. Bone mineral density, blood levels of vitamin D and calcium, phosphorus and alkaline phosphatase will be measured and their changes will be compared after six months of administration.

Participants/Inclusion and exclusion criteria
30 children under 15 years of age with acute lymphoblastic or myeloblastic leukemia referred to Tabriz Children Hospital. Children with chronic leukemia and under 2 years old will not be included in the study.

Intervention groups
Alendronate group: 30 children with acute leukemia will be given alendronate for six months.

Main outcome variables
Bone density; serum calcium levels; serum vitamin D; Serum alkaline phosphatase levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200916048733N1**
Registration date: **2020-10-30, 1399/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-30, 1399/08/09**
Update count: **0**

Registration date
2020-10-30, 1399/08/09

Registrant information
Name
Azim Rezamand
Name of organization / entity
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Iran (Islamic Republic of)
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+98 41 3526 2280
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-02, 1398/12/12

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Evaluation of The effects of Alendronates on Osteopenia in Children with Acute Leukemia

Public title
The Effect of Alendronate in the Treatment of Osteopenia due to Acute Leukemia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Children under 15 years Children with acute

lymphoblastic leukemia Children with acute myeloblastic leukemia

Exclusion criteria:

Children with chronic leukemia Children under 2 years

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **1**

Two blood samples before and after the medication

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research Vice-Chancellor, 3rd floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5154300633

Approval date

2020-03-02, 1398/12/12

Ethics committee reference number

IR.TBZMED.REC.1398.1268

Health conditions studied

1

Description of health condition studied

Acute Lymphoblastic Leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

2

Description of health condition studied

Acute Myeloblastic Leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

Serum level of vitamin D

Timepoint

Measurement of serum vitamin D levels at baseline (before intervention) and six months after Alendronate administration

Method of measurement

Enzyme-linked Immunosorbent assay (ELISA)

2

Description

Serum level of Calcium

Timepoint

Measurement of serum calcium levels at baseline (before intervention) and six months after Alendronate administration

Method of measurement

Biochemistry auto-analyzer

3

Description

Serum level of Phosphorus

Timepoint

Measurement of serum phosphorus levels at baseline (before intervention) and six months after Alendronate administration

Method of measurement

Biochemistry auto-analyzer

4

Description

Bone density

Timepoint

Bone density evaluation at baseline (before intervention) and six months after Alendronate administration

Method of measurement

Dual Energy X-ray Absorptiometry (DEXA)

5

Description

Serum Alkaline Phosphatase levels

Timepoint

Measurement of serum alkaline phosphatase levels at the beginning of the study (before the intervention) and six months after the use of alendronate

Method of measurement

Biochemistry auto-analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients with acute leukemia for six months alendronate with the chemical composition of alendronate sodium, tablets with a concentration of 70 mg, with a dose of 35 mg once a week or 5 mg once daily orally, company Hashtgerd Iran Pharmacy will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Laleh Tokhmechian

Street address

Tabriz Children Hospital, Sheshgelan Street.

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Phone

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dr.tokhmechian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Research Vice-Chancellor, 3rd floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street.

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research-vice@tbzmed.ac.ir

Web page address

https://researchvice.tbzmed.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Laleh tokhmechian

Position

Rezident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

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
All personal data of the study participants can be shared after the individuals are not identified. The study protocol will be published after its completion and the clinical study report will be available.

When the data will become available and for how long
The access period will start 6 months after the results are published.

To whom data/document is available
The data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Use of data including demographic characteristics and blood test results and DEXA scan will be allowed in clinical trial and meta-analysis studies.

From where data/document is obtainable
Laleh Tokhmechian dr.tokhmechian@yahoo.com

What processes are involved for a request to access data/document
Personal details including name and surname, place of work, place of study should be provided. Type of study, sample size, study objectives, place of study should also be mentioned. After completing the study and printing the results, the data will be presented as an article.

Comments