

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of alendronate in prevention of steroid- induced osteopenia in childhood ALL and NHL

Protocol summary

Summary

The aim of this double blind clinical trial is to determine the preventive effect of alendronate in steroid- induced osteopenia in childhood ALL or NHL. In this study 30 children with ALL or NHL will be selected purposefully and will be randomized to receive 35 mg alendronate /week for 6 months or control group (without any effective treatment for osteopenia). Demographic information and medical history will be recorded in all patients. BMD will be done and compared at first and after 6 months (at the end of the study) in both groups. Informed consent form is essential inclusion criteria and patients non-compliance with treatment will be excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202279155N1**

Registration date: **2012-03-24, 1391/01/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-24, 1391/01/05

Registrant information

Name

Afsane Akhondzadeh

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1223 5605

Email address

akhondzadeh@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak university of medical sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of alendronate in prevention of steroid-induced osteopenia in childhood ALL and NHL

Public title

Evaluation of alendronate in prevention of steroid-induced osteopenia in childhood ALL and NHL

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: children with ALL or NHL; informed consent form exclusion criteria: Patient or parents desire to leave the study; Non-compliance with treatment regimen

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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.

City

Arak

Postal code

Approval date

2011-09-11, 1390/06/20

Ethics committee reference number

90-114-9

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukaemia

ICD-10 code

C91

ICD-10 code description

Acute lymphoblastic leukaemia

2

Description of health condition studied

Non-Hodgkin lymphoma

ICD-10 code

C85.9

ICD-10 code description

Non-Hodgkin lymphoma, unspecified

3

Description of health condition studied

osteoporosis

ICD-10 code

M81.4

ICD-10 code description

Drug-induced osteoporosis

Primary outcomes

1

Description

BMD

Timepoint

0, 6months after drug administration

Method of measurement

Bone densitometry of neck of femur and spins

Secondary outcomes

1

Description

sever allergic reaction

Timepoint

every week

Method of measurement

history and physical examination

2

Description

gastro intestinl problems

Timepoint

every week

Method of measurement

history and physical examination

Intervention groups

1

Description

case: cap alenderonate 35 mg/ week for 6 months

Category

Treatment - Drugs

2

Description

control group: without treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir kabir hospital

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr. Said Changizi Ashtiyani

Street address

Deputy of Reserch, Arak University of Medical Siences, Sardasht, Arak.

City

Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Afsane Akhondzadeh

Position

resident of pediatrics

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

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Person responsible for scientific

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Contact**Name of organization / entity**

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Full name of responsible person

Dr. Aziz Eghbali

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Assistant professor, sub specialist of pediatrics

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty