Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 alendronatein steroid- induced osteopenia in childhood ALL or NHL. In this study 30 children with ALL or NHL will selected purposefully and will 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 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

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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
osteoprosis
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 densitometery 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
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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
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Full name of responsible person
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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