Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the effect of oral Allopurinol on liver function test in childhood leukemia in maintenance therapy phase

Protocol summary

Study aim
Evaluation of the effect of oral Allopurinol on liver function test in childhood leukemia in maintenance therapy phase

Design
Clinical trials with control group, randomized assignment to intervention and control groups with systematic coding without blindness, with a sample size of 40

Settings and conduct
This clinical trial study will carry out in children with acute lymphatic leukemia referred to Mirkabir Arak Hospital, who are being treated with Mercaptopurine in the maintenance phase of the disease. The patients will be coded according to the order of entry and randomly divided into two groups of intervention and the control group. The intervention group will receive the Allopurinol tablet. There will not be any intervention in the control group. All subjects entering the trial will be checked in terms of the level of liver enzymes including bilirubin, ALT, AST, and ALP. Patients will be monitored for 6 months by measuring their level of liver enzymes on a monthly basis and will be compared in two groups at the end of 6 months.

Participants/Inclusion and exclusion criteria
Entry requirements: All children with acute lymphocytic leukemia treated with Mercaptopurine Exit conditions:Parental dissatisfaction; Renal failure; Hepatitis B; Hepatitis C; AIDS

Intervention groups
The intervention group that is treated with Mercaptopurine will also receive Allopurinol oral tablet. The control group is only treated with Mercaptopurine .

Main outcome variables
Alanine Aminotransferase; Aspartate Aminotransferase; Alkaline Phosphatase; Total Bilirubin; Direct Bilirubin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190107042281N1**
Registration date: **2019-08-20, 1398/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-20, 1398/05/29**
Update count: **0**

Registration date
2019-08-20, 1398/05/29

Registrant information

Name
Roya Shaykh-Baygloo

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3313 4715

Email address
royashb@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-01, 1398/03/11

Expected recruitment end date
2019-11-16, 1398/08/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of oral Allopurinol on liver function test in childhood leukemia in maintenance therapy phase

Public title
Evaluation of the effect of oral Allopurinol on liver function test in childhood leukemia in maintenance therapy phase
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with acute lymphocytic leukemia treated with mercaptopurine
Exclusion criteria:
Parental dissatisfaction Renal failure Hepatitis B Hepatitis C AIDS
Age
From **2 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Systematic codes so that the eligible patients will be coded according to their entrance, meanwhile patients with odd codes will be categorized in control group and who with even codes will be categorized in Intervention group.
Blinding (investigator's opinion)
Not 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 madical science., Basij square., Sardasht., Arak
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2018-11-04, 1397/08/13
Ethics committee reference number
IR.ARAKMU.REC.1397.194

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]

Primary outcomes

1

Description
Alanine Aminotransferase
Timepoint
Measurement of serum Alanine Aminotransferase (ALT) levels At the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of allopurinol administration
Method of measurement
blood test

2

Description
Aspartate Aminotransferase
Timepoint
Measurement of serum Aspartate Aminotransferase (AST) levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of allopurinol administration
Method of measurement
blood test

3

Description
Alkaline Phosphatase
Timepoint
Measurement of serum Alkaline Phosphatase (ALP) levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of allopurinol administration
Method of measurement
blood test

4

Description
Total Bilirubin
Timepoint
Measurement of serum Total Bilirubin levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of allopurinol administration
Method of measurement
blood test

5

Description
Direct Bilirubin
Timepoint
Measurement of serum Direct Bilirubin levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of allopurinol administration
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Allopurinol tablet receive 4 mg /kg/ day and up to 200 mg daily, divided into two doses.
Category
Prevention

2

Description
Control group: There is no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital
Full name of responsible person
Aziz Eghbali
Street address
Amir Kabir Hospital, Parastar Square, Shahid Shiroodi Street
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Arak
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aziz_eghbali@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Arak University of Medical Sciences., Basij Square; Sardasht; Arak
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3848176341
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research@arakmu.ac.ir
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
Roya Shaykh Baygloo
Position
General physician
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Aziz Eghbali

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatric hematology oncology

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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
General physician

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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

Title and more details about the data/document
The main data used in the analysis will be shared

When the data will become available and for how long
Access date: 6 months after printing the results

To whom data/document is available
Scientific researchers

Under which criteria data/document could be used
It can be used only in scientific research

From where data/document is obtainable
Email of the research executives

What processes are involved for a request to access data/document
1- Introducing research subject and researcher's organizational affiliation 2- Declaration of research objectives 3- Declaration of data usage process 4- Setting up research cooperation memorandum between research executives and applicants of data

Comments