# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
**City**
Arak
**Province**
Markazi
**Postal code**
3819691187
**Phone**
+98 86 3313 4715
**Fax**
**Email**
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
**City**
Arark
**Province**
Markazi
**Postal code**
3848176341
**Phone**
+98 86 3417 3645
**Email**
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
**Street address**
Arak Amirkabir Hospital, Parastar Square, Shahid Shiroodi Street
**City**
Arak
**Province**
Markazi
**Postal code**
3819691187
**Phone**
+98 863313471519
**Email**
royashb@yahoo.com

## 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

**Street address**
Arak Amirkabir Hospital, Parastar Square., Shahid Shiroodi Street

**City**
Arak

**Province**
Markazi

**Postal code**
3819691187

**Phone**
+98 86 3313 4715

**Email**
aziz_eghbali@yahoo.com

## Person responsible for updating data

**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

**Street address**
Arak Amirkabir Hospital, Parastar Square., Shahid Shiroodi Street

**City**
arak

**Province**
Markazi

**Postal code**
3819691187

**Phone**
+98 86 3313 4715

**Email**
royashb@yahoo.com

## 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**