

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the effect of oral liversol on liver enzymes in patients with Leukemia in the Preservative Phase

#### Protocol summary

##### Study aim

Evaluation of the effect of oral liversol on liver enzymes in patients with Leukemia in the Preservative Phase

##### Design

Clinical trial with a control group with parallel groups, one-blind, randomized.

##### Settings and conduct

This study was carried out as a clinical trial at the Pediatric Clinic of Amir Kabir Hospital in Arak on patients with leukemia, also the study will also be single blinded in which patients will be blinded in study. This assessment is a clinical trial in Phase 3, the children who are diagnosed with leukemia in the preservative phase and approved by a specialist physician are considered as a study group. In this study, 40 children who have entered the criteria are selected. Patients are categorized based on blocked randomization method, 20 children in the intervention group (recipient of the liversol) and 20 children in the control group (recipient of the placebo). Accordingly, the status of liver enzymes is evaluated initially and then monthly for 6 months after starting treatment.

##### Participants/Inclusion and exclusion criteria

Patients over 5 years of age with leukemia in the preservative phase referred to Amir Kabir hospital in Arak, with informed consent in the study, impaired hepatic enzymes (AST And ALT greater than 60), total cholesterol above 200, total bilirubin more than 2, and Gamma glutamyl transpeptidase more than 60 are enrolled in the study, also patients with other blood diseases and liver diseases such as HBV, HCV and HIV excluded from the study.

##### Intervention groups

In the intervention group, people aged below 12 years of age, 70 mg and over 12 years of age, 140 mg of liversol tablets for two times per day, in the control group, the same placebo is used two per day.

##### Main outcome variables

Liver Enzymes Level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150119020715N10**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **prospective**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

##### Registration date

2019-06-16, 1398/03/26

##### Registrant information

##### Name

Aziz Eghbali

##### Name of organization / entity

دانشگاه علوم پزشکی اراک

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3465 5314

##### Email address

dr.eghbali@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-21, 1398/03/31

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of oral livergol on liver enzymes in patients with Leukemia in the Preservative Phase

## Public title

Effect of oral livergol on liver enzymes in patients with Leukemia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients over 5 years of age with leukemia in the preservative phase referring to Amir Kabir hospital in Arak Informed consent of the participants in the study Disrupted liver enzymes (AST and ALT greater than 60). Total cholesterol above 200 Total bilirubin equal to or greater than 2 GGT more than 60

### Exclusion criteria:

With other blood diseases and liver diseases such as HBV, HCV and HIV

## Age

From 3 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

A simple randomization is done with sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B they will be tested

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This means that patients in groups do not know the used drugs, and drugs has similar packaging, two drugs are similar in color, two drugs are similar in taste and odor.

## Placebo

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

Sardasht

#### City

Arak

#### Province

Markazi

#### Postal code

3848176941

#### Approval date

2019-01-21, 1397/11/01

#### Ethics committee reference number

IR.ARAKMU.REC.1397.292

## Health conditions studied

### 1

#### Description of health condition studied

Leukemia in the Preservative Phase

#### ICD-10 code

C95.9

#### ICD-10 code description

Leukemia, unspecified

## Primary outcomes

### 1

#### Description

Liver Enzymes

#### Timepoint

Before treatment, with a month's interval in six month from starting treatment

#### Method of measurement

Blood tests

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In cases under 12 years of age take 70 mg and over 12 years of age take 140 mg of Liverghol oral pills two times per day, for 6 months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The same placebo take two times per day, for 6 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Department of Pediatrics, Amir Kabir hospital

**Full name of responsible person**

Roghaie Rahimi Afzal

**Street address**

Amir Kabir hospital, Basij Square, Arak.

**City**

Arak

**Province**

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**Postal code**

3819693345

**Phone**

+98 86 3313 5075

**Email**

mahmoodrezaie069@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Arash Anoushirvani

**Street address**

Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak.

**City**

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dr.eghbali@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**

Aziz Eghbali

**Position**

Blood specialist and oncology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

Amir-Kabir Hospital, Basij Square, Arak, Iran

**City**

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**Email**

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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 of Pediatric oncology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Aziz Eghbali

**Position**

Associate Professor of Pediatric oncology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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