

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

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

Protocol summary

Study aim

Evaluation of the effect of oral livergol 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 livergol) 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 livergol 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

Markazi

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

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 5075

Email

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

Arak

Province

Markazi

Postal code

3819693345

Phone

+33 135075

Email

dr.eghbali@arakmu.ac.ir

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

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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