

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Silybum marianum in treatment and prevention of hepatotoxicity in patients undergoing induction therapy for acute lymphoblastic leukemia

Protocol summary

Summary

This is a Single-Blinded interventional study, in which children aged under 15 with a diagnosis of acute lymphoblastic leukemia undergoing induction therapy, randomly treated with Silybum marianum and Placebo with a mean dose of 5 mg/kg daily for 28 days. Patients with liver diseases or diabetes were not involved. Laboratory tests were done in patients on days 0, 28 and 56 and results were recorded and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080717325N2**

Registration date: **2014-08-27, 1393/06/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-27, 1393/06/05

Registrant information

Name

Afshin Fathi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1226 1610

Email address

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-21, 1392/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Silybum marianum in treatment and prevention of hepatotoxicity in patients undergoing induction therapy for acute lymphoblastic leukemia

Public title

Silybum marianum in treatment and prevention of hepatotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children aged under 15 with a diagnosis of acute lymphoblastic leukemia undergoing induction therapy Exclusion criteria: Patients with liver diseases or diabetes

Age

From **30 days** old to **14 years** old

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)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ardabil University of Medical Sciences

Street address

Daneshgah St, Janbazan Sq

City

Ardabil

Postal code**Approval date**

2013-01-20, 1391/11/01

Ethics committee reference number

Arums1032

Health conditions studied**1****Description of health condition studied**

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia

Primary outcomes**1****Description**

Reduces hepatotoxicity of chemotherapy

Timepoint

In first visit, Day 28, Day 56

Method of measurement

Enzymatic

Secondary outcomes**1****Description**

Fasting blood glucose

Timepoint

In first visit, Day 28, Day 56

Method of measurement

In first visit, Day 28, Day 56

2**Description**

Side effects

Timepoint

In first visit, Day 28, Day 56

Method of measurement

In first visit, Day 28, Day 56

Intervention groups**1****Description**

Silybum marianum 5 mg/kg daily for 28 day in case group

Category

Prevention

2**Description**

Zinc sulfate 5 mg/kg daily for 28 day in control group

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bu - Ali Hospital

Full name of responsible person

Dr. Afshin Fathi

Street address

Varzesh Sq. Ardabil

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Parvane Naftchi

Street address

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City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes
Title of funding source
Ardabil 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

Name of organization / entity
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Person responsible for updating data

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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