

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluating silymarin effects on cardiac and hepatic side effects of chemotherapy drug in children with acute lymphoblastic leukemia

Protocol summary

Summary

Objectives: The purpose of this study is to investigate the effect of taking Silymarin on reducing the cardiovascular and liver complications caused by the chemotherapy drugs in children with acute lymphocytic leukemia.

Methods: In a randomized clinical trial, children aged 2 to 14 years with acute lymphocytic leukemia referring to the Isfahan Seyed-al-Shohada hospital who have undergone at least 6 months of maintenance treatment and don't have a history of heart and kidney disease and do not eat any medication except chemotherapy drugs, randomly based on a random numbers table will place in both intervention and control groups (at least 20 patient in each group). Intervention group receive Silymarin (5 milligrams per kilogram of body weight) in addition to chemotherapy drugs (included: Purinetol 75 mg and Methotrexate 20 mg per square meter body surface area) daily for 6 months and the control group receive only above chemotherapy drugs. Cardiac function by echocardiography and measuring Creatine kinase-Muscle and Brain (CK-MB) and lactate dehydrogenase enzymes and Liver complications by measuring aminotransferases and alkaline phosphatase and also coagulation tests including prothrombin time and partial thromboplastin time will be investigated at baseline, 3 and 6 months after Silymarin administration in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071935175N1**

Registration date: **2017-08-18, 1396/05/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-18, 1396/05/27

Registrant information

Name

Nahid Reisi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3235 0210

Email address

reisi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating silymarin effects on cardiac and hepatic side effects of chemotherapy drug in children with acute lymphoblastic leukemia

Public title

Protective effects of silymarin on cardiac and hepatic side effects of chemotherapy drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of ALL based on bone marrow morphology and immunophenotype; Age 2-14 years; Therapy in maintenance phase of childhood ALL (at least 6 months); Exclusion criteria: Previous history of liver and heart disease; Take any other medicines except chemotherapy drug

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran

City

Isfahan

Postal code

8174673461

Approval date

2015-05-13, 1394/02/23

Ethics committee reference number

IR.MUI.REC.1394.3.213

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description

Liver enzymes: Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Alkaline phosphatase (ALP)

Timepoint

Before, 3 and 6 months after intervention

Method of measurement

Blood test

2

Description

Cardiac function

Timepoint

Before, 3 and 6 months after intervention

Method of measurement

Echocardiography, measuring enzyme Creatine kinase-Muscle and Brain (CK-MB) and Lactate Dehydrogenase (LDH)

3

Description

Coagulation testes: Prothrombin Time (PT), activated Partial Tromboplastin Time (aPTT) and International Normal Ratio (INR)

Timepoint

Before, 3 and 6 months after intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Ejection Fraction (EF)

Timepoint

Before, 3 and 6 months after intervention

Method of measurement

Ecocardiography

2

Description

Cardiac Systolic Function (SF)

Timepoint

Before, 3 and 6 months after intervention

Method of measurement

Ecocardiography

Intervention groups

1

Description

Chemotherapy associated with Livergol Tablet (containing 70 mg Silymarin) 5mg/kg/day/PO/ in 2 divided doses/ half an hour before meal [Goldaru Pharma Com, Iran]

Category

Treatment - Drugs

2

Description

Control group: Routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed-al-Shohada Hospital

Full name of responsible person

Nahid Reisi

Street address

Farshadi Alley, Khayam St., Seyed-al-Shohada Hospital, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

DR Mehdi Nematbakhsh

Street address

Vice chancellor for research, Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran, 81746 73461

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Nahid Reisi

Position

Pediatric Oncologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr Nahid Reisi

Position

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Other areas of specialty/work

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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