Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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. Metods: 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

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Nahid Reisi
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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), activeted 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 (contaning 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
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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