Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The Evaluatin of Effectiveness of the Milk Testhile for Hepatoxicity in Children with Acute Lymphoblastic Leukemia(ALL)

Protocol summary

Study aim

Determination of the Effect of Milk Testile on the Treatment of Hepatotoxicity Caused by Chemotherapy Drugs in Children with Acute Lymphoblastic Leukemia (ALL)

Design

In this study, 50 patients with Acute Leukemia and admission to the study who are referred to the Oncology Clinic of Motahari Hospital in Urmia are selected.Participants are randomly divided into intervention and control groups and each participant is assigned a code

Settings and conduct

Shahid Motahari Hospital in Urmia This study is double-blinded under a controlled trial after approval at the research committee of Shahid Motahari Hospital and the Medical Ethics Committee of Urmia University of Medical Sciences for 50 children with ALL referred to the Oncology Clinic of Urmia Martyr Motahari Hospital in the age group under 15 years old in The maintenance phase of the standard treatment will be in accordance with the Standards of the International Institute of Cancer In order to control the errors, the study will be blinded, so that for all individuals, special codes will be taken and the researcher as well as the participants themselves will not be aware of their status and grouping status.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are: 1) ALL diagnosis based on the criteria of the International Institute of Cancer with initial involvement of more than 20% of bone marrow 2) Hepatotoxicity of Grade 2 and 3 in each of the following four cases based on the criteria of the International Institute of Cancer: Aminoalanine Transferase (ALT); Aspartate Aminotransferase (AST); Total Bilirubin (TB) 3) ALL patients in the chemotherapy maintenance phase. 4) ALL patients, 15-2 years old 5) Patients ALL Pre Bcell, Early Pre Bcell Exit criteria are: Exit criteria are: 1) Unwillingness to participate in the study 2) Extra bile duct obstruction, severe liver or kidney failure, gastrointestinal obstruction, malabsorption syndrome, viral hepatitis 3) Grade 4 hepatotoxicity 4) Sepsis-induced hepatotoxicity 5) Intolerance to Oral Fluoride 6) Deny the patient to study and continue taking the medication 7) No regular and daily intake of medication 8) Gastritis and other complications associated with taking Lourgal 9) History of allergy due to previous use of lorogel

Intervention groups

Children with ALL referred to Oncology Clinic of Urmia Shahid Motahari Hospital in the age group under 15 years of age who maintains standard care in accordance with the criteria of the International Institute for Cancer

Main outcome variables

Serum AST level Serum ALT level Serum level of Billi T Serum level of Billi D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170821035831N2**
Registration date: **2018-02-14, 1396/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-14, 1396/11/25**
Update count: **0**

Registration date

2018-02-14, 1396/11/25

Registrant information

Name

parvaneh shadara

Name of organization / entity

medical university

Country

Iran (Islamic Republic of)

Phone

+98 914 435 8549

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ketabat.f@umsu.ac.ir

Recruitment status
Recruitment complete
Funding source
urmia medical university

Expected recruitment start date
2017-04-19, 1396/01/30
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
 The Evaluatin of Effectiveness of the Milk Testhile for Hepatoxicity in Children with Acute Lymphoblastic Leukemia(ALL)

Public title
Livergol Effect on Decrease of Hepatotoxicity caused by Chemotherapy Drugs
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ALL diagnosis based on the criteria of the International Institute of Cancer with initial involvement of more than 20% of bone marrow Hepatotoxicity of Grade 2 and 3 in each of the following four cases based on the criteria of the International Institute of Cancer: Aminoalanine Transferase (ALT); Aspartate Aminotransferase (AST); Total Bilirubin (TB) ALL patients in the chemotherapy maintenance phase. ALL patients, 15-2 years old Patients ALL Pre Bcell, Early Pre Bcell
Exclusion criteria:
Unwillingness to participate in the studyl Extra bile duct obstruction, severe liver or kidney failure, gastrointestinal obstruction, malabsorption syndrome, viral hepatitis Grade 4 hepatotoxicity Sepsis-induced hepatotoxicity Intolerance to Oral Fluoride Deny the patient to study and continue taking the medication No regular and daily intake of medication Gastritis and other complications associated with taking Lourgal History of allergy due to previous use of loroge
Age
From **30 days** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Block
Blinding (investigator's opinion)
Double blinded
Blinding description
To randomize, the blocked randomization method will be used Given that the sample size in each group is 24, and a total of 48 people are considered, and according to its multiplicity, the permutations of the combination AAA and BBB will be used.First, all AAA BBB malformations will be written for each mode, and then all possible combinations will be mixed.Of the allocated codes, the lot number 8 (with respect to the other blocks will be 6 equal to 8 blocks will be selected) will be selected and then allocated to the alternate groups based on the selected numbers and alternate combinations.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia Medical University
Street address
Motahari Hospital Kashani Street Urmia West Azarbaijan
City
Urmia
Province
West Azarbaijan
Postal code
57146-15436
Approval date
2017-04-19, 1396/01/30
Ethics committee reference number
ir.umfu.rec.1396.5

Health conditions studied

1

Description of health condition studied
Acute lymphoblastic leukaemia [ALL]
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Liver Enzyme (AST ALT Bill Total & Direct)
Timepoint
Befor Intervention , 35 and 70 days after intervention
Method of measurement
Microgram Per Litrer(for Liver Enzyme) - Miligram Per Deciliter(for Billi)

Secondary outcomes

empty

Intervention groups

1

Description
Treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology Clinic Motahari Hospital
Full name of responsible person
Dr.Farid Ghazizade
Street address
Motahari Hospital Kashani Street Urmia West Azarbaijan
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Postal code
5714615463
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ketabat.f@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia Medical University
Full name of responsible person
Dr.Farid Ghazizade
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Postal code
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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
Urmia Medical University
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
Urmia Medical University
Full name of responsible person
Dr.Farid Ghazizade
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Title and more details about the data/document
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Start the access period after printing the results
To whom data/document is available
Physicians and Researchers in Clinical Sciences
Under which criteria data/document could be used
With the permission of the relevant organization (Urmia University of Medical Sciences)
From where data/document is obtainable
With the permission of the relevant organization (Urmia University of Medical Sciences) Dr. Farid Ghazizadeh 09141769856
What processes are involved for a request to access data/document
Referring to Urmia University of Medical Sciences Vice-Chancellor for Research and obtaining a written letter from the Deputy Chairperson and presenting it to Dr Ghazizadeh
Comments