Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the effect of oral chicory extract on liver enzymes in patients with acute lymphoblastic leukemia: A clinical trial

Protocol summary

Study aim

Determining the effect of chicory extract on liver enzymes in patients with acute lymphoblastic leukemia

Design

This study is a double-blinded clinical trial with a parallel design and a control group. The study population will include all eligible children with acute lymphoblastic leukemia referred to Mohammad Kermanshahi Hospital. A total of 110 eligible people will be selected conveniently. A table of random numbers is used for randomization and the participants will assigned to two intervention and control groups

Settings and conduct

Mohammad Kermanshahi Hospital. The patient receives syrup extract daily, and by measuring liver tests, if they worsen, they are dropped from the study.

Participants/Inclusion and exclusion criteria

ALL children whose blood levels of liver enzymes are more than 2-4 times normal are included in the study, and in case of hepatitis and liver failure, they are excluded from the study.

Intervention groups

Intervention group: The patient should take some chicory plant extract as a supplement daily, and liver tests will be measured at the beginning of the study, 1.5 months, 3 months and 6 months later, and will be recorded in a special form in case of deterioration. The patient's liver conditions will be excluded from the study. The patient will be in this study for 6 months, and during this period, the patient's blood should be taken four times in Mohammad Kermanshahi Hospital to check the level of liver enzymes. Control group: Half of the patients are given a placebo (zinc sulfate syrup) daily. Finally, the result of the study will be for the treatment of cancer patients.

Main outcome variables

Serum bilirubin level, Level of liver enzymes AST, Level of ALT liver enzymes,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220526055001N1**
Registration date: **2022-11-16, 1401/08/25**
Registration timing: **retrospective**

Last update: **2022-11-16, 1401/08/25**
Update count: **0**

Registration date

2022-11-16, 1401/08/25

Registrant information

Name

Sima Shareghi ghahreman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 7368

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sara.kooti@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-14, 1401/06/23

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral chicory extract on liver enzymes in patients with acute lymphoblastic leukemia: A clinical trial

Public title
Efficacy of chicory plant syrup on liver enzymes in patients with acute lymphoblastic leukemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with acute lymphoblastic leukemia (ALL) who have blood levels of liver enzymes more than 4-2 times normal are included in the study In the consent form, giving the participants the right to choose to participate or not to participate in the research and to keep the information confidential A written consent form from the child or their parents is the moral obligation of the researcher not to impose costs on the patients
Exclusion criteria:
In case of hepatitis and liver failure, they will be excluded from the study.
Age
To **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random method. 110 cards are selected and numbers from 1-110 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. If this number is 0, 1, 2, 3, 4, it will be assigned in the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second intervention group
Blinding (investigator's opinion)
Double blinded
Blinding description
The current study is a double blind clinical trial study. The observer and statistician do not know about the allocation of people to the intervention and control groups. To blind the observer, a person outside the research team performs the liver tests on the patients and does not know the type of medicine that the patients receive. For the purpose of blinding the statistician, the coded data is provided to him for analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2022-04-24, 1401/02/04
Ethics committee reference number
IR.KUMS.MED.REC.1401.004

Health conditions studied

1

Description of health condition studied
Acute lymphoblastic leukemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description
Level of ALT liver enzymes
Timepoint
The beginning of the study, one and a half months, three and six months after the end of the study
Method of measurement
blood test

2

Description
Level of liver enzymes AST
Timepoint
The beginning of the study, one and a half months, three and six months after the end of the study
Method of measurement
blood test

3

Description
Serum bilirubin level
Timepoint
The beginning of the study, one and a half months, three and six months after the end of the study
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 5 cc chicory plant extract (Produced by Razi University Pharmaceutical Department)in the form of syrup as a daily supplement for one week to one and up to 3 months based on the level of liver enzymes.
Category
Treatment - Drugs

2

Description
The control group will receive zinc sulfate syrup as a placebo daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Mohammad Kermanshahi Superspeciality Hospital
Full name of responsible person
Dr. Mohammad Reza Golpaygani
Street address
Dr. Mohammad Kermanshahi Superspeciality Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Cyrus Jalili
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
50
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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Golpaygani
Position
Member of the academic staff of Kermanshah University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
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Hellal ahmar crossroad, Hosseinieh Andisheh Park
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Person responsible for scientific inquiries

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Kermanshah University of Medical Sciences

Full name of responsible person
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Position
Member of the academic staff of Kermanshah University of Medical Sciences

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Sima Shareghi Ghahraman

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Rezident

Latest degree
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Other areas of specialty/work
Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available