Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of Syrup based on Naqu Fawakeh on liver enzymes in children with ALL undergoing chemotherapy ,a double blind randomized controlled trial.

Protocol summary

Study aim
Determining the effect of herbal syrup Naqu Fawakeh in comparison to Silymarin on liver enzymes in children aged 5 to 17 years old with ALL under chemotherapy, a double-blind clinical trial

Design
This study is a controlled, parallel-group, double-blind, randomized, phase 3 clinical trial. For randomization the permutation block randomization method with four blocks will be used.

Settings and conduct
This study will be done in Imam Reza Clinic of Shiraz Faculty of Medical Sciences. According to the block randomization table (using the software), the patients are placed in two intervention groups by taking Naqu Fawake syrup and the control group by taking Silymarin syrup. To make the study blind, the drugs are in identical color and shape bottles , and a ten-digit code will be printed on each bottle. both patient and researcher are blinded to the study, but the statistical analyst is aware of the type of medication that the patients take.

Participants/Inclusion and exclusion criteria
Entry conditions: ALL Patients based bone marrow aspiration, immunophenotype, in treatment maintenance phase while taking methotrexate, 6-mercaptopuril, and have 2 or more times liver enzymes above the maximum normal level Non-entry : Allergy to herbal medicines or medicines that damage the liver. liver disease, HIV, diabetes, diarrhea, malignancies and chronic intestinal diseases

Intervention groups
Intervention group: 53 people take Fitobile syrup between the ages of 5 - 12 , 5cc 3 times a day, and ages 12-17 , 1 tablespoon 3 times a day, 3 hours after each meal. Control group: 53 people take Silymarin syrup, 2cc (children under 30kg), 4cc (children over 30kg) 3 times a day after meal.

Main outcome variables
Liver and kidney function tests, blood cell count, constipation, nausea and vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230810059110N1**
Registration date: **2023-11-01, 1402/08/10**
Registration timing: **prospective**

Last update: **2023-11-01, 1402/08/10**
Update count: **0**

Registration date
2023-11-01, 1402/08/10

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-06, 1402/08/15
Expected recruitment end date
2024-08-21, 1403/05/31
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of Syrup based on Naqu Fawakeh on liver enzymes in children with ALL undergoing chemotherapy ,a double blind randomized controlled trial.

Public title
Investigating the effect of Syrup based on Naqu Fawakeh on liver enzymes in children with ALL undergoing chemotherapy ,a double blind randomized controlled trial.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ALL based on bone marrow aspiration and immunophenotype, aged 5 to 17 years, in the maintenance phase of treatment by methotrexate and 6-mercaptopuril, with liver enzymes level 2 times or more higher than the maximum normal level Willingness to participate in the study .
Exclusion criteria:
The occurrence of any allergy and intolerance to the drug. Diagnosis of liver disease during planning. The patient's unwillingness to continue treatment. Taking drugs that interfere with the herbs in the composition. history of drug sensitivity to the plants in the syrup:Prunus cerasus,Prunus domestica,Alhagi pseudalhagi ,Zizyphus jujube,Cordia myxa ,Tamarindus indica,Prunus armeniaca,Saccharum officinarum The patient has diarrhea. (CTCAE questionnaire)[39] history of liver disease, viral hepatitis, HIV, diabetes, other malignancies, and chronic intestinal disease. Taking drugs with the risk of cholestatic liver damage or damaging liver cells: drugs causing liver cholestasis: amoxicilline and clavulanic acid with consumption of more than 90 mg per kilogram per day, anabolic steroids, chlorpromazin, clopidogrel, erythromycin, irbesartan, mirtazapine, estrogen , terbinafine, drugs that damage liver cells and cause liver cholestasis, amitriptyline, azathioprine: captopril, carbamazepine, clindamycin, co-trimoxazole, cyproheptadine, enalapril, flutamide, nitrofurantoin, phenobarbital, phenytoin, sulphonamide, trazodone, verapamil
Age
From **5 years** old to **17 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
The permutation block randomization method with blocks of four will be used (using random allocation software). This method is one of the most widely used random methods that guarantees equality of groups to a large extent. For this purpose, first we name the groups A or B. then we consider the different permutations of 4 letters of these two letters, of course, you can also consider the blocks with the size of 2 and 6, etc. But blocks with size 4 have been used more. Four permutations of two letters A and B are AABB, ABAB, ABBA, BBAA, BABA, BAAB. Each of these is a block of size 4, which includes two Patients from the experimental group and two from control Patients , for example, AABB permutation means that the first and second Patients are selected from group A (group A can be the test or the control group) and The second two Patients are assigned to group B (group B can be the experiment or the control group), then randomly by throwing a coin, we determine which A or B are the experiment group and which one is control group, for example, suppose A is the experimental group and B is the control group. Then we assign each of these 6 permutations to the numbers from 1 to 6 in the following order. 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB Now, using the table of random numbers, we extract numbers from the table sequentially, and we consider the digit of the extracted random numbers, which are one of the numbers 0 to 9, and depending on whether one of the numbers 1 to 6 comes, each of the blocks We select the numbers assigned to these numbers. With this calculation, we need 27 random numbers, which we use the rule of using the table of random numbers to extract these 27 numbers until 27 blocks of 4 are selected. If the numbers 0, 7, 8, and 9 come, we ignore them and continue this order to provide a complete list for the entire sample volume. Randomization using a computer can also be used for implementation in this regard. The randomization sequence is determined by the statistician in coordination with the pharmacist. The questioner enters the participants into the plan and determines the block of each patient according to the variables, then each patient is given a code, and according to that, the bottle with the corresponding code label is delivered to the patient by the trained personnel in the pharmacy of Imam Reza Hospital. The questioner does not know the contents of the bottles. Hide the random allocation, ten-digit codes will be printed on the bottles in coordination with the statistician and the pharmacist. The codes related to each block are randomized, identified and provided to the patient by the interviewer before the initial evaluation, and Naqu Fawakeh (Fitobile) and Silymarin (Livertrap) syrup are in bottles that are completely similar in color and shape. and similar labels are attached to the company's bottle.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and service providers are blinded to the

intervention until the end of the design and presentation of statistical results. Naqoo Fawake Syrup (Fitobile) and Silymarin (Livertrap) are in completely similar bottles in terms of color and shape, and similar labels are attached to the company's bottles. To hide the random allocation, ten-digit codes will be printed on the bottles in coordination with the statistician and the pharmacist. The codes related to each randomized block are specified and provided to the patient by the interviewer before the initial evaluation. The pharmacist is aware of the contents of the bottles (Effervescence and Silymarin). The statistician who prepares the blocks and tables of random numbers is aware of the content of the codes. In order to blind the researcher, after the visit and receiving the relevant code, the patient goes to Imam Reza Pharmacy to receive the medicine, and the medicine is delivered to the patient based on the code by the trained staff of the pharmacy, and the way to take the medicine is given to the patient and his companion based on age and weight. They explain.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand St., Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2023-06-26, 1402/04/05

Ethics committee reference number
IR.SUMS.MED.REC.1402.302

Health conditions studied

1

Description of health condition studied
Elevation of liver enzymes caused by chemotherapy

ICD-10 code
K71.6

ICD-10 code description
Toxic liver disease with hepatitis, not elsewhere classified

Primary outcomes

1

Description
Alanine transaminase (ALT)

Timepoint
before the start of the intervention and 28, 84, 56 days after the start of the drug

Method of measurement
Blood test

2

Description
Aspartate transaminase(ASP)

Timepoint
before the start of the intervention and 28, 84, 56 days after the start of the drug

Method of measurement
Blood test

3

Description
Alkaline Phosphatase(ALP)

Timepoint
before the start of the intervention and 28, 84, 56 days after the start of the drug

Method of measurement
Blood test

Secondary outcomes

1

Description
Constipation

Timepoint
At the beginning of the study (before the start of the intervention) and 28, 56, 84 days after the start of the drug

Method of measurement
Criteria Terminology Common For Adverse Events (CTCAE) version4 ,questionnaire

2

Description
Nausea and Vomiting

Timepoint
At the beginning of the study (before the start of the intervention) and 28, 56, 84 days after the start of the drug

Method of measurement
MAT questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: Naqu Fawake syrup containing Bukhara plums, black plums, mangosteens, jujubes, jaggery, tamarinds, apricots, and red sugar, which is currently manufactured under the brand name of Fitobile Syrup by Faratab Company, in the amount of 5 cc 3 times a day, 3 hours later Each meal at the age of 5 to 12 years and 1 tablespoon a day 3 hours after each meal at the age of 12 to 17 years is given for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Control group: The control group is given silymarin syrup from Hakim Momin Tabrizi company and according to the amount of 120 mg of silymarin per 5 cc, in children under 30 kg 2 cc 3 times a day after each meal and for children over 30 Kilo 4 cc is given 3 times a day after each meal

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic, Shiraz University of Medical Sciences

Full name of responsible person

Fariba Ettehadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Yasman Vazani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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
Confidentiality

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