Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of the traditional wheat product (saviq) on the pattern of changes caused bychemotherapy in the gastrointestinal tract of children with acute lymphoblastic leukemia referred to the Imam Rezaclinic in 1401 - a triple-blind clinical trial

Protocol summary

Study aim

Determining the effect of traditional wheat bran product on reducing the incidence of chemotherapeutic gastrointestinal complications in children with acute lymphoblastic leukemia undergoing chemotherapy

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 58 patients. For randomization in this study, the Restricted randomization method of block randomization has been used.

Settings and conduct

Samples were randomly selected from children aged 3 to 18 years with acute leukemia undergoing chemotherapy referred to Imam Reza's clinic in Shiraz and were divided into case and control groups. Intervention period: 4 weeks Before starting the study, patients will be divided into two groups A and B based on the attached checklist by block randomization method. The patient-level study will evaluate the outcome and statistically analyze the results. Only the drug maker can decode the contents of each sachet based on the original form stored in the randomization results. The person in charge of drug delivery, the patient, the doctor and the person in charge of evaluating the consequences will not know about the codings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 3-18 years old with lymphoblastic leukemia undergoing chemotherapy Conditions of non-admission: Children in very serious condition and with a ban on treating physicians or candidates for surgery and extensive antibiotic treatment

Intervention groups

The traditional product "Wheat saviq with jollab" is given as a "complementary food" and "refined wheat flour with jollab equivalent syrup" as "placebo" is given to the case and control groups.

Main outcome variables

Prevention of gastrointestinal symptoms (diarrhea, constipation, bloating, dyspepsia, anorexia, nausea, vomiting, abdominal pain) in patients in the intervention group compared to the control group

General information

Reason for update

Correcting the sample size based on the correct and realistic criteria and announcing the end of sampling (The size of the initial sample was not based on realistic formulas and criteria, and due to the limitation in the number and low cooperation of children and parents in the cancer department, it was necessary to revise and correct it. Due to the special conditions and the limitation of the number of children with entry conditions To study, the previously mentioned number was somehow not possible.) Modified sample volume formula: In order to compare the average of the intended outcomes between the two sample size groups, taking into account the type 1 error and the power equal to 5 and 80% and the effect size equal to 0.8 (based on Cohen's criterion and due to the lack of a similar study in the studied population, i.e. children with leukemia) equal to 52 people (26 people in each group) was calculated using GPower software. Therefore, taking into account the dropout error equal to 10%, the final sample volume was determined to be 58 people (29 people in each group).

Acronym

IRCT registration information

IRCT registration number: **IRCT20220410054474N1**
Registration date: **2022-05-24, 1401/03/03**
Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**

Update count: **1**

Registration date

2022-05-24, 1401/03/03

Registrant information

Name

Saba Barkhori mehni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

2022-06-07, 1401/03/17

Actual recruitment end date

2023-06-10, 1402/03/20

Trial completion date

2023-06-10, 1402/03/20

Scientific title

Evaluating the effects of the traditional wheat product (saviq) on the pattern of changes caused bychemotherapy in the gastrointestinal tract of children with acute lymphoblastic leukemia referred to the Imam Rezaclinic in 1401 - a triple-blind clinical trial

Public title

Evaluating the effects of the traditional wheat product (saviq) on the pattern of changes caused bychemotherapy in the gastrointestinal tract of children with acute lymphoblastic leukemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 3-18 years with severe lymphoblastic leukemia treated in the post-consolidation period.

Exclusion criteria:

Severely ill patients Patients who must be prescribed fasting by physician Patients with broad-spectrum antibiotics Patients with active infection Patients with celiac disease Those requiring gastrointestinal surgery Neutropenic patients

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **58**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization 1- Sequence generation (method used to generate random allocation sequence) 2- Randomization type, details of any constraints In this study, we will use the restricted randomization method of block randomization. The size of all blocks is equal and in this two-group experiment we will have 4 blocks (including 2 participants in the intervention group and 2 participants in the control group). For each of the 6 possible cases for the quadruple block, the numbers are assigned as follows. AABB=1, ABAB=2, BBAA=3, BABA=4, ABBA=5, BAAB=6 With the help of a table of random numbers, the numbers between 1 and 6 are selected and the treatment allocation list is determined according to each number. In this three-blind trial, in addition to patients, researchers and analysts are unaware of which person is receiving the drug or placebo. Only the drug maker can decode the contents of each sachet based on the original form stored in the randomization results. Participant allocation concealment method (mechanism used to randomize participant allocation (such as consecutive numbered containers) and explain all the steps that can be taken to hide the sequence until the intervention is assigned to each group We use concealment allocation, which is the method used to execute random sequences on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed in random sequence (envelopes opaque, sealed, numbered Sequentially) In this method, each of the random sequences created is recorded on a card and the cards are placed in envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. (Who determines the random allocation sequence? Who enters the study participants? Who assigns the participants to the intervention groups?) A trained person outside the research team is responsible for randomly assigning patients, and at the time of registration of participants, they provide the participant with one of the sealed letter envelopes according to the order of entry of eligible participants. Put it to deliver to the researcher and he after opening the envelope, the group assigned to that participant, is determined for him and delivers the medicine package.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Before starting the study, patients will be divided into two groups A and B based on the attached checklist by block randomization method. Supplemental and placebo sachets will also be divided into containers labeled A and B by the drug manufacturer. Group A patients will

receive drug A and group B patients will receive drug B. Study at the patient level, outcome assessor and statistical analyzer of the results will be blinded. Only the manufacturer of the drug can decode the contents of each sachet based on the original form stored in the randomization results. The person in charge of drug delivery, the patient, the doctor and the person in charge of evaluating the consequences will not know about the codings. The results of the two groups will be submitted to the statistical analyst under the headings of groups A and B.

Placebo

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

Persian medicine school, 9th floor, Medicine school, Zand street

City

shiraz

Province

Fars

Postal code

۷۱۳۴۸۴۵۷۹۴

Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.SUMS.MED.REC.1400.622

Health conditions studied

1

Description of health condition studied

Acute Lymphoblastic Leukemia

ICD-10 code

C91.01

ICD-10 code description

Acute lymphoblastic leukemia, in remission

Primary outcomes

1

Description

Occurrence of gastrointestinal symptoms

Timepoint

Beginning and end of the intervention; Days 0 and 28

Method of measurement

Pediatrics Quality of Life Questionnaire - gastrointestinal symptoms scales version 3.0

Secondary outcomes

1

Description

"Quality of life" of children - "Weight" of the child - "Blood test (CBC)" - "Gastrointestinal microbiome" - "Number of colonies created by the collection of bacteria in the feces"

Timepoint

All variables will be measured on day 0 and day 28 after the intervention.

Method of measurement

TAPQOL Quality of Life Questionnaire for Preschool Children (1-6 years old) and PedsQL Questionnaire for Quality of Life of Preschool Children- "Weight" of the child on day 0 and day 28 after the intervention"Blood test (CBC)" to check for blood factors including WBC Plt Hb RBC on day 0 and day 28 after intervention - "Stool test" of the child and performing Real-Time PCR to measure and determine the gastrointestinal microbiome on day 0 and day 28 after the intervention- Counting the number of colonies created by the collection of bacteria in the feces by microdilution culture on day 0 and 28 of the intervention

Intervention groups

1

Description

Intervention group: Intervention group: The traditional product of "wheat bran" is given to the case group as a "complementary food". It should be eaten once a day for four weeks. The time of consumption of the food composition is one meal a day and preferably in the middle of the morning meal. The product is given to the mother in the form of powder and the recipe is as follows: mix with boiling water and add Jollab syrup (which is given to the mother along with medicine sachets) and cook it briefly until it becomes halva. Jollab syrup (a combination of rose, saffron and sugar) is delivered to the mother ready with sachets containing soybean. The method of combining suviq and jollab will be explained to the mother both in writing and orally.Remove the resulting mixture from the heat and after it has cooled a little, add 2-3 tablespoons of syrup, according to the dose of saviq.A short video of the work process was also sent to them. Product: Whole wheat saviq with jollab syrup - Jollab syrup preparation formula: three liters of rose water per kilogram of sugar + half a pound of saffron (about two grams) _ daily consumption of children depending on their age and weight between 20-30 grams Saviq. The jollab syrup is purchased from a pharmaceutical company and saviq is produced by the pharmacist of the study.

Category

Other

2

Description

"Refined wheat flour" is given to the control group as a placebo. It should be eaten once a day for four weeks. The time of consumption of the food composition is one meal a day and preferably in the middle of the morning meal. The placebo is given to the mother in the form of powder and the recipe is as follows: Placebo syrup (which is given to the mother along with placebo sachets) and cook it briefly until it becomes halva. In the placebo group, a syrup with the same color, taste and aroma of jalab is given, which is without rose and saffron and contains only a small amount of essential oil. The method of mixing flour and syrup will also be explained to the mother in writing orally. Remove from the heat and after it has cooled a little, add 2-3 tablespoons of syrup, depending on the dose of flour) (a short video of the steps will be sent to them. The daily consumption of children, depending on their age and weight, is between 20-30 grams per day. The syrup used in the study is purchased from a pharmaceutical company and the consumed flour is purchased from a specific brand in the market.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza clinic

Full name of responsible person

Mani Ramzi

Street address

Imam Reza (AS) Specialized and Sub-Specialized Clinic, next to Namazi Hospital, Namazi S, Shiraz

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Shiraz

Province

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Web page address

https://emamreza.sums.ac.ir/page-EmamRezaClinic1/fa/91

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Vahid Hosseini

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Central Building of Shiraz University of Medical Sciences and Health Services, Opposite Palestine St., Zand st, Shiraz

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President_d@sums.ac.ir

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

65

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

2

Sponsor

Name of organization / entity

Research Center for Traditional Medicine and History of Medicine

Full name of responsible person

Majid Nimruzi

Street address

Research Center for Traditional Medicine and Medical History, Eighth Floor, Building No. 2, School of Medicine, Imam Hossein (AS) Square, Shiraz

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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

Research Center for Traditional Medicine and History of Medicine

Proportion provided by this source
35
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
Saba Barkhori mehni
Position
PhD student
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saba.barkhori@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Part of the data can be shared, such as information about demographic characteristics and its main outcome.
When the data will become available and for how long
The access period starts six months after the results are published
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Only for researchers who want to do meta-analysis and systematic review

From where data/document is obtainable

zohalinm@sums.ac.ir Mohammad Ebrahim Zahlinezhad Assistant Professor of Persian Medicine and History of Medicine 00989173026200

What processes are involved for a request to access data/document

Evaluation of the letter and details of the request by the supervisor and the main executor of the project And presentation of the issue in the weekly group meeting Estimated time: about two weeks

Comments