Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of high protein parenteral nutrition containing amino acid solution, dextrose, and lipid based on soybean oil with SMOFlipid and royal jelly on gut microbiota composition in post hematopoietic stem cell transplantated acute leukemia children

Protocol summary

Study aim

Determination and Comparison of the Effects of a Parenteral High-Protein Diet Containing an Amino Acid Solution, Dextrose, and Soybean Oil-Based Lipid with SMOFlipid and Royal Jelly on the Composition of Intestinal Microbiota in Children with Acute Leukemia Following Hematopoietic Stem Cell Transplantation (HSCT)

Design

Intervention Group 1: SMOFlipid and placebo; Intervention Group 2: SMOFlipid and royal jelly; Control Group: Intralipid and placebo. This is a controlled, double-blind, phase 3 clinical trial involving 30 patients who were randomized using block randomization.

Settings and conduct

Study Location: Tehran Pediatric Medical Center Study; Population: Children with acute leukemia who are candidates for HSCT; Type of Blinding: Double-blind; Method of Blinding: Each lipid dose is completely wrapped in foil, ensuring that the type of lipid remains concealed. Royal jelly and placebo capsules are administered in identical forms, with the same taste and consistency.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acute leukemia undergoing HSCT; informed consent; age over 2 and under 18 years; indication for starting parenteral nutrition. Exclusion criteria: presence of specific disease or renal/hepatic failure; allergy to peanut/soy; allergy to fish; serum triglyceride levels above 200 at the beginning of the study

Intervention groups

Intervention Group 1: SMOFlipid and Placebo (intravenous lipid injection combined with oral intake of a capsule identical to royal jelly containing a placebo). Intervention Group 2: SMOFlipid and Royal Jelly (intravenous lipid injection combined with oral intake of royal jelly capsules). Control Group: Intralipid and Placebo (intravenous lipid injection combined with oral intake of a capsule identical to royal jelly containing a placebo).

Main outcome variables

Fecal microbial species; Fecal microbial products (short-chain fatty acids)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250302064907N1**
Registration date: **2025-05-04, 1404/02/14**
Registration timing: **prospective**

Last update: **2025-05-04, 1404/02/14**
Update count: **0**

Registration date

2025-05-04, 1404/02/14

Registrant information

Name

Melika Hajimohammadebrahim-Ketabforoush

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-06-20, 1404/03/30
Expected recruitment end date
2026-06-19, 1405/03/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of high protein parenteral nutrition containing amino acid solution, dextrose, and lipid based on soybean oil with SMOFlipid and royal jelly on gut microbiota composition in post hematopoietic stem cell transplantated acute leukemia children

Public title
Studying the Effects of SMOFlipid and Royal Jelly on the Intestinal Microbiota of Children with Acute Leukemia Undergoing Hematopoietic Stem Cell Transplantation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with acute leukemia who are undergoing hematopoietic stem cell transplantation Informed consent obtained through legal guardians Individuals aged over 2 years and under 18 years Children Indicated for Initiating Parenteral Nutrition
Exclusion criteria:
The presence of specific diseases, as well as kidney and liver failure Peanut and soy allergy Fish allergy Serum triglyceride levels exceeding 200 at baseline.
Age
From **2 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization Double blocks, Sealed Envelope with Random Numbers The assignment of patients to each group and the distribution of envelopes will be at the sole discretion of the ward secretary. Randomization will be conducted using the block randomization method, which involves creating blocks of three. In this approach, one group is designated as A, the second as B, and the third as C. These letters are then arranged into blocks of three, resulting in six possible configurations for the arrangement of the letters. A random number between 1 and 6 will be generated by a calculator, and the blocks will be organized according to the order of the generated numbers. Based on this order, each patient entering the study will be assigned to one of the groups, following the sequence established within the blocks of three. Additionally, we will implement stratified randomization to ensure that patients are matched as closely as possible based on age and gender, thereby minimizing the risk of overmatching.
Blinding (investigator's opinion)
Double blinded
Blinding description
The Intralipid and SMOFlipid bottles in the pharmacy will initially be covered with aluminum foil, ensuring that only the pharmacy manager is aware of the distinction between them. The group receiving royal jelly is positioned opposite the control groups, both of which will receive SMOFlipid, while the group receiving Intralipid will also be administered a placebo. The company that manufactures the royal jelly capsules produces identical capsules that match the taste and consistency of the placebo. Neither the principal investigator nor the patients will know which type of product they are using.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No. 62, Children’s Medical Center, Gharib avenue
City
Tehran
Province
Tehran
Postal code
02166948444
Approval date
2024-06-16, 1403/03/27
Ethics committee reference number
IR.TUMS.CHMC.REC.1403.075

Health conditions studied

1

Description of health condition studied
Hematopoietic stem cell transplantation
ICD-10 code
تغذیه

ICD-10 code description
پیوند سلولهای بنیادی

Primary outcomes

1

Description
Fecal microbial species
Timepoint
Examination of stool samples for microbial species at the beginning of the study (before the intervention), on day 15, and on day 30 after the intervention.
Method of measurement
Laboratory kit for detecting fecal microbial species

Secondary outcomes

1

Description
Amount of fecal short-chain fatty acids
Timepoint
Before intervention_15 days, and 30 days after intervention
Method of measurement
High-performance liquid chromatography (HPLC)

Intervention groups

1

Description
Intervention group1: SMOFlipid+Placebo. Intravenous injection of SMOFlipid (Fresenius Kabi Co.,) at a dose of 0.5 to 1 gram per kg for a maximum of 10 days + oral administration of placebo in the form of capsules with a shape, taste, and consistency similar to royal jelly manufactured by Marine Co., 1000 mg capsules daily for 10 days.
Category
Treatment - Drugs

2

Description
Intervention group2: SMOFlipid + Royal jelly. Intravenous injection of SMOFlipid (Fresenius Kabi Co.,) at a dose of 0.5 to 1 gram per day for a maximum of 10 days + oral intake of royal jelly capsules manufactured by Marine Co., 1000 mg capsules daily for 10 days.
Category
Treatment - Drugs

3

Description
Control group: Intralipid + Placebo. Intravenous injection of Intralipid (Fresenius Kabi Co.,) at a dose of 0.5 to 1 gram per kg for a maximum of 10 days + oral administration of placebo in the form of capsules with a shape, taste, and consistency similar to royal jelly manufactured by Marine Co., 1000 mg capsules daily for 10 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center
Full name of responsible person
Prof. Amir Ali Hamidieh
Street address
No. 62, Children's Medical Center, Next to Imam Khomeini Hospital, Dr. Mohammad Gharib Ave., End of Keshavarz Blvd.
City
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Tehran
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1419733151
Phone
+98 21 6693 0024
Email
cmcpr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
Street address
6th Floor, Vice President for Research and Technology, Central University Organization, corner of Qods Ave., Keshavarz Blvd.
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Prof. Amir Ali Hamidieh

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Others

Street address

No. 62, Children's Medical Center, Next to Imam Khomeini Hospital, Dr. Mohammad Gharib Ave., End of Keshavarz Blvd.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Prof. Amir Ali Hamidieh

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Others

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Amir Ali Hamidieh

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Hematology and Oncology Specialist - Hematopoietic Stem Cell Transplantation

Street address

No. 62, Children's Medical Center, Next to Imam Khomeini Hospital, Dr. Mohammad Gharib Ave., End of Keshavarz Blvd.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

The data related to predefined outcome will be provided as an SPSS file that does not include any identifying information about the patients.

When the data will become available and for how long

The access period begins six months after the results are published.

To whom data/document is available

Interested doctors, researchers and students

Under which criteria data/document could be used

Sending the request via email.

From where data/document is obtainable

Melika Hajimohammadebrahim-Ketabforoush; ketabforoshm@gmail.com

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

The access period begins six months after the results are published, If the applicant is eligible.

Comments