Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness and safety of Royal Jelly on the number of white blood cells in patients with acute lymphoblastic leukemia

Protocol summary

Study aim

Determination of the effect of royal jelly on total white blood cells (WBC) in children with acute lymphoblastic leukemia (ALL) treated in Ali Asghar Pediatric Hospital

Design

A semi-experimental study of pre- and post-treatment clinical trials (phase 1), with 20 samples used as a pilot study. The sampling method will be in the available form.

Settings and conduct

This study will be performed in Ali Asghar Pediatric Hospital, Initially, patients with ALL will undergo a complete blood cell (CBC) test and will receive 2 g of royal jelly in oral form, daily for a period of 6 weeks and will be given a CBC test every 2 weeks. Every two weeks, if needed, depending on the response of the WBC to treatment, the amount of royal jelly will be increased (up to 3 times a day: 6 g) and after 6weeks the WBC changes, the ANC as well as the ALC in these patients will be compared to their baseline. WBC-enhancing drugs such as granulocyte colony-stimulating factor, will not be used.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with (ALL); undergoing complete maintenance and remission; Having a normal heart echo; No history of asthma; No history of allergy to honey and its products. Exclusion Criteria: underlying heart and pulmonary problem; A history of allergies to honey and its products;

Intervention groups

Children with ALL who are in maintenance or complete remission. The study will be performed on individuals before and after consuming royal jelly. Royal Jelly is a natural honey product that starts with a daily dose of 2 grams up to a maximum of three times a day. Patients are tested every two weeks and the dose is increased as needed. The control group is the same patients before the royal jelly was used, which is measured on the basis of experiments upon arrival.

Main outcome variables

White Blood Cell, Acute Neutrophil Count, Acute lymphocyte Count

General information

Reason for update

Determining the real sample size that performed and modifying the work method

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042260N1**
Registration date: **2020-05-26, 1399/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-29, 1399/04/09**
Update count: **1**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Rozhin Pahlevani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4431 9829

Email address

pahlevan.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

2020-02-20, 1398/12/01

Actual recruitment end date
2020-06-21, 1399/04/01
Trial completion date
2020-06-21, 1399/04/01

Scientific title
Evaluation of the effectiveness and safety of Royal Jelly on the number of white blood cells in patients with acute lymphoblastic leukemia

Public title
Royal Jelly in acute leukemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with acute lymphoblastic leukemia who are in the complete maintenance and remission phase. Having a normal heart echo No history of asthma No history of allergy to honey and its products
Exclusion criteria:
history of allergy to honey and its products history of asthma Cardiomyopathy and underlying heart problem
Age
To **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **26**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
The study is before and after type

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
No4, Elahieh 19, Elahieh Complex, end of Kuhsar Blvd, shahran, tehran,Iran
City
Tehran
Province
Tehran
Postal code
14888774645
Approval date
2019-08-18, 1398/05/27
Ethics committee reference number
IR.IUMS.FMD.REC.1398.173

Health conditions studied

1

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

Primary outcomes

1

Description
total White blood cell count
Timepoint
from beginning (before using a Jelly), then every two week until 6 weeks
Method of measurement
Complete blood count (CBC)

2

Description
acute lymphocyte count
Timepoint
from beginning (before using a Jelly), then every two week until 6 weeks
Method of measurement
Complete blood count (CBC) /Differential Cell Exam

3

Description
acute Neutrophil count
Timepoint
from beginning (before using a Jelly), then every two week until 6 weeks
Method of measurement
Complete blood count (CBC) /differential cell exam

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Children with acute lymphoblastic lymphoma (before entering the study and using a jelly). The gel used is Royal Jelly, which is a honey product that is completely natural and has an official license. Royal Jelly belongs to Khansar Company and the health monitoring ID is 10/15551. Dosage starts at two grams per day orally and is up to 12 grams three times a day. The patient is tested every two weeks and the dose is increased accordingly. Children with acute lymphoblastic leukemia will be screened before and after using royal jelly.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali asghar children`s hospital

Full name of responsible person
Rozhin Pahlevani

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No.4, Elahieh 19, Elahieh complex, End of koohsar Blvd., Shahran

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Pahlevan.r@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr Seyyed Abbas Motevalian

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Rozhin Pahlevani

Position
Pediatric resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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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
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
This study is a before-after phase 1 clinical trial, It will also be done as a Pilot, and the results can be shared.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Researchers, doctors

Under which criteria data/document could be used
This study is a small-scale, pilot study, and is expected to be investigated with a bigger sample size after termination.

From where data/document is obtainable
Rozhin pahlevani's Email Addresses: Pahlevan.r@iums.ac.ir Rozhin.pahlevan@gmail.com Rozhin_p92Yahoo.com

What processes are involved for a request to access data/document
Once the article is published, applicants can receive information about the data through the email addresses provided.

Comments