Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of royal jelly on blood cell count and fatigue in cancer patients undergoing chemotherapy.

Protocol summary

Study aim
Determining the effect of royal jelly on the number of blood cells and fatigue in cancer patients undergoing chemotherapy.

Design
Clinical trial with two intervention and control groups, one side blind, randomized on 64 cancer patients undergoing chemotherapy. The website https://www.sealedenvelope.com was used for randomization.

Settings and conduct
The current study is a clinical trial type, which will be conducted on cancer patients undergoing chemotherapy (outpatient and inpatient) after receiving permission and obtaining a letter of introduction from the ethics committee and vice president of research and technology of Zanjan University of Medical Sciences. A total of 64 samples will be included in the study and will be randomly divided into two intervention groups of 32 samples and a control group of 32 samples.

Participants/Inclusion and exclusion criteria
In this study, cancer patients undergoing chemotherapy, who have received at least two rounds of chemotherapy and are over 18 years old and have no history of allergy to honey and honey products, cardiovascular diseases and asthma, are included in the study.

Intervention groups
In cancer patients undergoing chemotherapy, Royal jelly will be consumed orally in the amount of one gram daily mixed in 10 grams of natural honey (concentration 10%) for five days in the morning fasting in the intervention group. In the control group, 10 grams of natural honey without royal jelly will be used daily as a placebo, fasting for five days.

Main outcome variables
First variable: Fatigue, which will be checked with Smets fatigue measurement tool. The second variable: the blood cell count that will be recorded based on the laboratory results.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230328057779N1**
Registration date: **2023-05-29, 1402/03/08**
Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**
Update count: **0**

Registration date
2023-05-29, 1402/03/08

Registrant information

Name
Alireza Ghane

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3314 8263

Email address
alirezagh2233175@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of royal jelly on blood cell count and fatigue in cancer patients undergoing chemotherapy.

Public title

Investigating the effect of royal jelly on blood cell count and fatigue in cancer patients undergoing chemotherapy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Cancer diagnosis recorded in the patient`s medical records Receiving at least two courses of chemotherapy drugs. Receiving drugs that suppress the bone marrow and cause pancytopenia with the approval and supervision of a respected oncology doctor. Age above 18 years. Consent to participate in the study. Physical and hemodynamics stability.

Exclusion criteria:

Having a history of cardiovascular diseases, asthma and diabetes. Having any major disabling medical and psychiatric conditions that would interfere with the evaluation. Having a history of allergy to honey and honey products. Age over 60 years

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

To assign the samples to the study groups randomly, the design of random permutation blocks of two groups with blocks of four will be used, with 32 samples in group A (intervention group) and 32 samples in group B (intervention group) control) will be considered. Then the website https://www.sealedenvelope.com will be used to determine the required random blocks and their sequence. Sealed envelopes will be used for concealment. In this way, based on the sequence of randomly determined blocks, cards with the letters A and B that show the sequence of allocation will be placed inside the envelope. Then, an envelope will be opened for each participant in the study, and based on the card inside the envelope, the participant will be assigned to the control or intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Sealed envelopes will be used for concealment. In this way, based on the sequence of randomly determined blocks, cards with the letters A and B that show the sequence of allocation will be placed inside the envelope. Then, an envelope will be opened for each participant in the study, and based on the card inside the envelope, the participant will be assigned to the control or intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2023-03-29, 1402/01/09

Ethics committee reference number

IR.ZUMS.REC.1402.019

Health conditions studied

1

Description of health condition studied

Stomach Cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

2

Description of health condition studied

Esophagus cancer

ICD-10 code

C15

ICD-10 code description

Malignant neoplasm of esophagus

3

Description of health condition studied

Malignant neoplasm of small intestine

ICD-10 code

C17

ICD-10 code description

Malignant neoplasm of small intestine

4

Description of health condition studied
Malignant neoplasm of colon
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

5

Description of health condition studied
Malignant neoplasm of rectum
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

6

Description of health condition studied
Malignant neoplasm of liver and intrahepatic bile ducts
ICD-10 code
C22
ICD-10 code description
Malignant neoplasm of liver and intrahepatic bile ducts

7

Description of health condition studied
Malignant neoplasm of bronchus and lung
ICD-10 code
C34
ICD-10 code description
Malignant neoplasm of bronchus and lung

8

Description of health condition studied
Malignant neoplasm of heart, mediastinum and pleura
ICD-10 code
C38
ICD-10 code description
Malignant neoplasm of heart, mediastinum and pleura

9

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Blood cell count includes the count of white blood cells, red blood cells, hemoglobin and platelets, which will be evaluated according to laboratory results.
Timepoint
After the end of the second round of chemotherapy, the intervention is carried out using royal jelly and placebo for five days. After two weeks from the end of the intervention, direct evaluation will be done by the researcher.
Method of measurement
Counting blood cells using laboratory results (CBC).

Secondary outcomes

1

Description
Fatigue is evaluated using the Smet's Multidimensional Fatigue Assessment Questionnaire, which ranges from 20 to 100, and a higher score indicates more fatigue.
Timepoint
After the end of the second round of chemotherapy, the intervention is carried out using royal jelly and placebo for five days. After two weeks from the end of the intervention, direct evaluation will be done by the researcher.
Method of measurement
assessing fatigue using a 20-item questionnaire, Smet's multidimensional measurement of fatigue (Multidimensional Fatigue Inventory).

Intervention groups

1

Description
Intervention group: 32 patients will be selected according to the inclusion criteria, using the available sampling method, who come in different work shifts and on different days of the week. After stating the objectives of the study in a meeting and obtaining consent from the patients, the patients enter the study. Demographic information of all participants will be recorded by the researcher. A training session will be held on how to store and use honey and royal jelly. Before receiving the third course of chemotherapy drug, blood parameters test (CBC) will be done and the answers will be recorded in the checklist. The MFI fatigue questionnaire will also be completed by the researcher before the intervention through an interview. Then, in the intervention group, royal jelly prepared from an accredited local apiary approved by the University of Medical Sciences, using cool boxes containing ice and maintaining the cold chain, will be provided to the patients at the time of the visit and they will be asked to finish Carry out the study of royal jelly and keep it in the refrigerator. 10 grams of natural honey containing one gram of royal jelly (10% concentration) will be consumed orally for five days in the morning on an empty stomach in the intervention group. Again, before receiving the next course of chemotherapy, blood parameters will be tested in the aforementioned laboratory. The questionnaire related to the measurement of fatigue will also be completed by the researcher before the start of the new course of chemotherapy through an interview. The data is then analyzed.

Category
Rehabilitation

2

Description
Control group: The number of 32 patients will be selected according to the inclusion criteria, using available sampling method, who come in different work shifts and on different days of the week. After stating the objectives of the study in a meeting and obtaining consent from the patients, the patients enter the study. Demographic information of all participants will be recorded by the researcher. A training session will be held on how to store and use honey and royal jelly. Before receiving the third course of chemotherapy drug, blood parameters test (CBC) will be done and the answers will be recorded in the checklist. The MFI fatigue questionnaire will also be completed by the researcher before the intervention through an interview. Then, in the control group, honey (placebo) prepared from an authentic local bee farm approved by the University of Medical Sciences, using cool boxes containing ice and maintaining the cold chain, will be provided to the patients during the visit and they will be asked to Keep the honey (placebo) in the refrigerator until the end of the study. 10 grams of natural honey will be consumed orally for five days in the morning fasting in the Control group. Again, before receiving the next course of chemotherapy, blood parameters will be tested in the aforementioned laboratory. The questionnaire related to the measurement of fatigue will also be completed by the researcher before the start of the new course of chemotherapy through an interview. The data is then analyzed.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Mousavi Hospital, Zanjan city

Full name of responsible person
Nasrin Hanifi - Reza Mansouri

Street address
Zanjan University of Medical Sciences - Ayatollah Mousavi Hospital

City
Zanjan

Province
Zanjan

Postal code
4513956184

Phone
+98 24 3314 8263

Email
nasrinhanifi@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Nasrin Hanifi

Street address
Faculty of Nursing, Zanjan University of Medical Sciences

City
Zanjan

Province
Zanjan

Postal code
4513956113

Phone
+98 24 3314 8318

Fax
+98 24 3314 8319

Email
nasrinhanifi@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Alireza Ghane

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing, Zanjan University of Medical Sciences

City
Zanjan

Province

Zanjan

Postal code
4513956113

Phone
+98 24 3314 8318

Email
alirezagh2233175@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Nasrin Hanifi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Zanjan University of Medical Sciences

City
Zanjan

Province
Zanjan

Postal code
4513956113

Phone
+98 24 3314 8336

Email
nasrinhanifi@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Alireza Ghane

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing, Zanjan University of Medical Sciences

City
Zanjan

Province
Zanjan

Postal code
4513956113

Phone
+98 24 3314 8318

Email
alirezagh2233175@gmail.com

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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data related to the age and gender of the study participants will be published after the end of the study.

When the data will become available and for how long
21/12/2023

To whom data/document is available
Researchers working in academic and scientific institutions.

Under which criteria data/document could be used
In conducting scientific research

From where data/document is obtainable
Mr. Alireza Ghane 09375780121 alirezagh2233175@gmail.com Dr. Nasrin Hanifi 09123422431 nasrinhanifi@zums.ac.ir

What processes are involved for a request to access data/document
A confirmation form from a university or scientific institute based on research work should be submitted.

Comments