# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**