Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of royal jelly on reducing symptoms of fatigue and weakness associated with chemotherapy in breast cancer

Protocol summary

Study aim
Determining the effect of royal jelly on reducing symptoms of fatigue and weakness associated with chemotherapy in breast cancer

Design
A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 50 patients. Using kitset.ir for randomization

Settings and conduct
Study patients in Shahid Modares Hospital, Tehran, in the intervention group will receive 1 oral capsule of royal jelly 2 times a day and in the control group, placebo for 2 weeks. Only the patients will be blinded and will not know about the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age below 60 years, confirmed diagnosis of breast cancer, hemoglobin > 8 g/dL, hematocrit > 30%, SGOT serum level < 3 times higher than normal, bilirubin < 2 mg/dl, creatinine < 2 mg /dl and normal thyroid test result Exclusion criteria: suffering from an underlying and chronic active inflammatory disease, simultaneous use of drugs affecting fatigue, metastatic patients with poor performance

Intervention groups
Each subject in the intervention group will take 1 oral capsule of royal jelly 2 times a day with water, and the control group will receive a placebo that will be similar in appearance, shape, color and smell to royal gel capsules. Patients will consume these capsules for 4 weeks.

Main outcome variables
Severity of weakness and fatigue after chemotherapy.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231226060535N1**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date
2023-12-29, 1402/10/08

Registrant information

Name
Tahere Fallahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 23871

Email address
taherefallahi52@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-10, 1402/10/20

Expected recruitment end date
2024-07-10, 1403/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of royal jelly on reducing symptoms of fatigue and weakness associated with chemotherapy in breast cancer

Public title
royal jelly and chemotherapy

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of breast cancer by laboratory and clinical evidence Hemoglobin > 8 g/dL Hematocrit > 30% SGOT serum level <3 times higher than normal Bilirubin level less than 2 mg/dl Creatinine less than 2mg/dl Normal thyroid test result
Exclusion criteria:
Having an underlying and chronic active inflammatory disease such as: RA, COPD, unstable cardiovascular disease, lung diseases such as asthma, uncontrolled pain, severe infection, pregnancy, severe depression Simultaneous use of drugs that can affect fatigue Metastatic patients with poor performance
Age
To **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method is used, in which the randomization unit is individual, and random sequence generation software (Random Number Generator software) is used. For concealment, non-transparent sealed envelopes with a random sequence is used . In this method, each random number created is recorded on a card and the cards are placed inside the envelopes in order.In order to maintain the random sequence of the envelopes on the outer surface, the numbering is done in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
After giving sufficient explanations to the patient about the studied groups, the participants will be assigned to one of the groups without informing them.For this purpose, the capsule with the same shape, size, color and smell as the royal jelly capsule will be used as a placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences Community Verified icon
Street address
Shhid Modarres highway
City
Tehran
Province
Tehran
Postal code
4631- 19395
Approval date
2023-07-25, 1402/05/03
Ethics committee reference number
IR.SBMU.MSP.REC.1402.224

Health conditions studied

1

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

Primary outcomes

1

Description
Severity of symptoms of fatigue
Timepoint
Measurement of symptoms of fatigue before the intervention and 14 days later
Method of measurement
by Visual Analogue Scale (VAS) and Fatigue Severity Scale (FSS) questionnaires

2

Description
Severity of symptoms of weakness
Timepoint
Measurement of symptoms of weakness before the intervention and 14 days later
Method of measurement
by Visual Analogue Scale (VAS) and Fatigue Severity Scale (FSS) questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Each subject in the intervention group will take 1 capsule of royal jelly twice a day after meals for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive a placebo that will be similar in appearance, shape, color and smell to the Royal Jelly capsules. Patients will consume the capsules twice a day after meals for 4 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modares Hospital
Full name of responsible person
Tahere Fallahi
Street address
Saadat Abad intersection,Yadgar Imam highway
City
Tehran
Province
Tehran
Postal code
۱۹۸۳۹۶۹۴۱۱
Phone
+98 21 23515
Email
pr_modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Zali
Street address
Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
4631- 19395
Phone
+98 21 2243 9872
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahere Fallahi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
4631- 19395
Phone
+98 21 2243 9872
Email
taherefallahi52@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elnaz Ataei
Position
Associate professor

Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
4631- 19395
Phone
+98 21 2243 9872
Email
taherefallahi52@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahere Fallahi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
4631- 19395
Phone
+98 21 2243 9872
Email
taherefallahi52@gmail.com

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
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available