

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

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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

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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

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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

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

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