Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effect of selenium supplemention on cancer-related fatigue in outpatient cancer patients and comparison of it with placebo effect in control group

Protocol summary

Study aim

The aim of this study was to evaluate the effect of selenium supplementation on cancer-related fatigue in cancer patients undergoing chemotherapy and to compare it with the placebo effect.

Design

A clinical trial with 70 patients, featuring a control group, parallel groups, and a triple-blind randomized design using a random number table.

Settings and conduct

Based on previous studies on the effects of pharmacological intervention on cancer-related fatigue in chemotherapy clinics affiliated to Isfahan University of Medical Sciences. Blinding the groups of clinicians, researchers and data analysts.

Participants/Inclusion and exclusion criteria

Inclusion criteria were 18 to 80 years of age and the presence of cancer-induced fatigue during chemotherapy

Intervention groups

Seleniumplus supplementation in intervention group and placebo administration in control group

Main outcome variables

The main outcome is the improvement of various parameters related to fatigue including physical weakness, etc. in patients.

General information

Reason for update

Subject: Request for Clinical Trial Information Update Dear Sir/Madam, I would like to request the following changes to the registered information of the clinical trial. The reasons for these changes are as follows: Participant Age Range: Please update the participant age range from "30-60 years" to "18-80 years." Reason: This change aims to broaden the scope of the study and achieve more comprehensive results by including a more diverse age group. Duration of Supplementation: Please adjust the supplementation duration from "6 weeks" to "4 weeks." Reason: This change is due to the shorter chemotherapy intervals for patients, making a 4-week supplementation period more accessible. Type of Supplement: In the original registration, only "selenium" was mentioned. However, the placebo was prepared with vitamins A, C, and E. If this adjustment had not been made, the control group would have been deprived of treatment, which is against ethical standards. Currently, the treatment group is receiving "Selenium Plus," while the control group is receiving "Selenium Plus without Selenium." This ensures that both groups are in similar conditions, with the only difference being the presence or absence of selenium. To enhance the credibility of the study, a triple-blind method will be implemented. In this approach, neither the participants, researchers, nor analysts will know the type of treatment being administered, which helps to reduce bias and increase the validity of the results. Thank you for your attention and cooperation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210825052293N1**
Registration date: **2021-10-03, 1400/07/11**
Registration timing: **prospective**

Last update: **2025-07-19, 1404/04/28**
Update count: **2**

Registration date

2021-10-03, 1400/07/11

Registrant information

Name

alireza mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 2744

Email address

alireza.mansory@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of selenium supplemention on cancer-related fatigue in outpatient cancer patients and comparison of it with placebo effect in control group

Public title

The effect of selenium on cancer related-fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 80 years of age To be able to read and write Definitive diagnosis of cancer which requires chemotherapy and has been confirmed with pathology findings and authenticated by an oncology subspecialist Not having another treatment regimen that has healing effect on fatigue To have cancer-related fatigue and score of 40 and above in fatigue questionnaire To tolerate oral medication To cooperate and agree with the study

Exclusion criteria:

Patients with known depression undergoing treatment Having anemia Having a disease that prevents patient from continuing participation in study When more than 20% of the questionnaire has not been completed Pregnancy and lactation Renal failure Taking medications such as baloxavir, marboxil, deferiprone, cabotegravir, bisphosphonate derivatives, bictegravir, dolutegravir, eltrombopag, trientine, raltegravir, penicillamine, elvitegravir Known allergy to selenium Hypothyroidism Skin cancer and individulas at high risk for developing squamous cell carcinoma

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Group Allocation and Coding: In this clinical trial, the drugs (Selenium Plus and Selenium Plus without Selenium) were divided and coded into two groups, "A" and "B," by a pharmacology professor acting as the supervisor. This supervisor is also blinded to the contents of each group to prevent any potential bias. Administration of the Drugs: Neither the participants nor the researchers know which group receives which treatment. As such, the patients are unaware whether they are receiving Selenium Plus or the placebo (Selenium Plus without Selenium), and the doctors administering the treatment are similarly blinded to the type of drug being given. Data Analysis: Upon completion of the study and data collection, the statistical analysis is carried out by analysts who are also unaware of which group received the actual drug and which received the placebo. This ensures that the statistical results are free from bias. Final Unblinding: After the statistical analysis is completed, the pharmacist supervisor, who holds the group codes, reveals the information. At this stage, it is disclosed which group received Selenium Plus and which received Selenium Plus without Selenium.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The secretary introduced the patients to the oncologist using randomized grouping and the oncologist provided treatments for each patient based on their group. The researcher, in cooperation with the oncologist, supervised the patient's use of the drug. Data available from questionnaires completed by the patients, were analyzed by a statistician specialist with respect to the confidentiality of the grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar jarib

City

Isfahan

Province
Isfehan
Postal code
8174673461
Approval date
2021-05-08, 1400/02/18
Ethics committee reference number
IR.MUI.MED.REC.1400.098

Health conditions studied

1

Description of health condition studied
Cancer-related fatigue
ICD-10 code
R53.0
ICD-10 code description
Neoplasm-related fatigue

Primary outcomes

1

Description
Cancer-related fatigue
Timepoint
Zero, 2 weeks, 4 weeks
Method of measurement
Multivariable questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: In this group, patients will take one 200 µg capsule of Selenium Plus once daily for 2 weeks, after which they will complete the fatigue questionnaire. They will then continue taking the capsule for an additional 2 weeks, totaling 4 weeks of treatment. Finally, they will complete the questionnaire once more. The results will be analyzed using SPSS version 26.
Category
Treatment - Drugs

2

Description
Control Group: In this group, patients will take a placebo once daily for 2 weeks, after which they will complete the fatigue questionnaire. They will then continue taking the placebo for an additional 2 weeks, totaling 4 weeks. Finally, they will complete the questionnaire once more. The results will be analyzed using SPSS version 26.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra clinics
Full name of responsible person
Ali Hajigholami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Vice Chancellery for Research and Technology, Hezar Jarib St
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Isfahan
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Postal code
8174673461
Phone
+98 31 3668 8138
Email
askari@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Alireza Mansouri

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
Internal Medicine

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data in the study except for personal data can be shared.

When the data will become available and for how long
The start of the access period is 6 months after the results are printed.

To whom data/document is available
At the current stage,the results will be available to researchers at university institutes.

Under which criteria data/document could be used
In terms of data analysis and analysis for academic researchers and use in later studies.

From where data/document is obtainable
School of social medicine,Isfahan
Ali_hajigholami@yahoo.com

What processes are involved for a request to access data/document
By submitting a written request to the director of the Social Medicine School, Isfahan

Comments