Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Curcumin on Fatigue, Sleep Quality, and Appetite in Women with Breast Cancer Undergoing Chemotherapy: A Clinical Trial

Protocol summary

Study aim
To determine the effect of curcumin on fatigue, sleep quality, and appetite in women with breast cancer undergoing chemotherapy

Design
Clinical Trial, by using block randomization, the Patients enter in intervention, or control group, A pilot study including10 patients from each group, will determine the size of the sample, Parallel groups, triple-blind

Settings and conduct
This study is a triple-blind clinical trial conducted at Kowsar Hospital in Semnan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Breast cancer diagnosis at least six months or more, Women undergoing chemotherapy, Women over 18 years of age, Sleep quality higher than 5 on the Pittsburgh scale, Informed consent to participate in the study. Exclusion criteria:Discontinuation of chemotherapy, Intolerance to curcumin or history of sensitivity to curcumin, Failure to fully participate in the one-month period, Voluntary withdrawal, History of mental disorders, Unstable medical conditions or concomitant diseases, Hospitalization during the study, History of cancer-related surgery, Metastasis to other sites, Death during the study.

Intervention groups
The intervention group received 500 mg of Curcumin Longa tablets once a day with lunch for one month, in addition to their routine regimen. The control group received a placebo tablet once a day with lunch for one month, also in addition to their routine regimen.

Main outcome variables
Sleep quality, fatigue, and appetite

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110427006318N17**
Registration date: **2025-07-28, 1404/05/06**
Registration timing: **prospective**

Last update: **2025-07-28, 1404/05/06**
Update count: **0**

Registration date
2025-07-28, 1404/05/06

Registrant information

Name
Monir Nobahar

Name of organization / entity
Semnan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-08-16, 1404/05/25

Expected recruitment end date
2027-02-14, 1405/11/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Curcumin on Fatigue, Sleep Quality, and Appetite in Women with Breast Cancer Undergoing Chemotherapy: A Clinical Trial

Public title
The Effect of Turmeric on Fatigue, Sleep Quality, and Appetite in Women with Breast Cancer Undergoing Chemotherapy: A Clinical Trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
- Breast cancer diagnosis at least six months or more - Women undergoing chemotherapy - Women over 18 years of age - Sleep quality higher than 5 on the Pittsburgh scale - Informed consent to participate in the study
Exclusion criteria:
- Discontinuation of Chemotherapy - Intolerance to curcumin or a history of sensitivity to curcumin - Failure to fully participate in the one-month period - Voluntary withdrawal - History of mental disorders - Unstable medical conditions or concomitant diseases - Hospitalization during the study - History of cancer-related surgery - Metastasis to other sites - Death during the study
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
The research sample assigned to the groups of the study by permuted blocks randomization. The samples are randomly divided into two intervention and control groups using blocks of six (the age and disease stage strata are used in the block division). Regarding age, the first patient is randomly placed in the intervention or control group, and the next patient with a maximum age difference of 5 years is placed in the other group. If the age difference between the next patient and the next patient is more than 5 years, the patient is randomly placed in another age block. Randomization is also conducted separately for disease stage. In this manner, the first patient at each disease stage is randomly assigned to either the intervention or control group, and the next patient with the same disease stage is placed in the opposite group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is a triple-blind randomized clinical trial. In this study, 500 mg turmeric tablets and placebo tablets are administered by the treating physician to patients in two groups: the intervention group and the control group. Only the treating physician is aware of the group assignments. Consequently, the patients participating in the study, the principal investigator, the questionnaire collector, and the data analyst remain unaware of the group allocations.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی سمنان
Street address
Semnan University of Medical Sciences, Basij Boulevard, Semnan
City
Semnan
Province
Semnan
Postal code
3513138111
Approval date
2025-07-21, 1404/04/30
Ethics committee reference number
IR.SEMUMS.REC.1404.120

Health conditions studied

1

Description of health condition studied
Women with breast cancer undergoing chemotherapy
ICD-10 code
(C50-C50)
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Sleep quality
Timepoint
At the beginning of the study and after one month
Method of measurement
Using the Pittsburgh Sleep Quality Index.

Secondary outcomes

1

Description
Fatigue
Timepoint
At the beginning of the study and after one month
Method of measurement
Using the Cancer Fatigue Scale

2

Description
Appetite
Timepoint
At the beginning of the study and after one month
Method of measurement
Using a Visual Analog Scale

Intervention groups

1

Description
Intervention group: The intervention group will receive one 500 mg turmeric tablet once a day with lunch for one month, in addition to their routine diet.
Category
Treatment - Other

2

Description
Control group: The control group will receive one placebo tablet once a day with lunch for one month, also in addition to their routine diet
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar hospital
Full name of responsible person
Monir Nobahar
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Faculty Nursing and Midwifery, Semnan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Abbas-Ali Vafaei
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Monir Nobahar
Position
Professor
Latest degree
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Other areas of specialty/work
Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Data is confidential

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

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

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available