Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of coenzyme Q10 on prevention of peripheral neuropathy induced by Paclitaxel and improving the quality of life in women with non metastatic breast cancer: a randomized, double-blind clinical trial study

Protocol summary

Study aim
Evaluation of the protective effect of Coenzyme Q10 in Preventing Paclitaxel-induced Peripheral neuropathy and Improving Quality of Life in Patients with Non-Metastatic Breast Cancer

Design
A Phase III double-blind, parallel-group randomized controlled trial will conducted on 210 patients, equally assigned to an intervention group receiving Coenzyme Q10 and a control group receiving placebo (105 patients per group), using block randomization with blocks of four.

Settings and conduct
This double-blind study, conducted in Hamadan during 2025–2026, will randomly assign eligible patients to receive either Coenzyme Q10 or a placebo. The aim is to assess Coenzyme Q10’s effect on peripheral neuropathy and quality of life. Both patients and outcome assessors will be blinded to group allocation, with only the treating physician informed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18–65 with breast cancer, scheduled for Paclitaxel chemotherapy, ECOG-PS: 0–2, completion of full treatment course and no history of diabetes or neuropathic conditions, Exclusion criteria: prior chemotherapy, warfarin use, pregnancy, severe allergy to Coenzyme Q10, or ECOG status 3–4.

Intervention groups
This study examines the effect of daily Coenzyme Q10 versus placebo(300mg daily with the same pills), administered throughout paclitaxel chemotherapy in breast cancer, on the incidence and severity of peripheral neuropathy and quality of life promotion. Neuropathy is evaluated pre- and post-treatment using questionnaires and Electrodiagnostic tests(NCS), with weekly assessments of quality of life and treatment side effects using EORTC-QLQ-CIPN20 and NCI-CTCAE v5.0.

Main outcome variables
Incidence of peripheral neuropathy, severity of peripheral neuropathy, quality of life promotion, and frequency of treatment-related adverse events، all compared between the intervention and control groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210308050628N2**
Registration date: **2025-08-29, 1404/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-29, 1404/06/07**
Update count: **0**

Registration date
2025-08-29, 1404/06/07

Registrant information

Name
Kamal Mohammadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of coenzyme Q10 on prevention of peripheral neuropathy induced by Paclitaxel and improving the quality of life in women with non metastatic breast cancer: a randomized, double-blind clinical trial study

Public title

Investigation of the Effect of Coenzyme Q10 on Neuropathy and Quality of Life in Chemotherapy-Treated Breast Cancer Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Adult women aged 18 to 65 years No history of chemotherapy Histological confirmation of breast cancer Non-metastatic status confirmed by paraclinical findings, including CT scan, bone scan, or PET-CT scan ECOG-PS: 0-2 No history of diabetes or other underlying neuropathic conditions

Exclusion criteria:

Prior administration of chemotherapeutic agents ECOG-PS: 3-4 Co-administration of Warfarin pregnancy Hypersensitivity to supplements containing Coenzyme Q10

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

This study employs block randomization to allocate participants into intervention and control groups. Blocks of four are used, each represented by a small box containing four balls: two marked with the letter "A" (intervention group) and two with the letter "C" (control group). For each patient, the treating physician randomly draws one ball from the box, and the patient is assigned to the corresponding group. After four patients have been enrolled, the next block is used. Participants in the intervention group receive Coenzyme Q10, while those in the control group are administered a placebo. The study is conducted in a double-blind manner, meaning that both patients and outcome assessors are blinded to group allocation. Only the treating physician is aware of the group assignments. Data are collected in a coded format to ensure confidentiality and minimize the risk of bias during data collection and analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted in a double-blind manner, where both the patients and the outcome assessors are blinded to group allocation. Only the treating physician will be aware of the group assignments. All data will be collected in a coded format to ensure confidentiality and minimize bias.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

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Shahid Fahmideh Blvd

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6517838736

Approval date

2025-07-28, 1404/05/06

Ethics committee reference number

IR.UMSHA.REC.1404.281

Health conditions studied

1

Description of health condition studied

Chemotherapy induced Neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The incidence and severity of neuropathy,

Timepoint

Before and One week after completion of chemotherapy

Method of measurement

NCI-CTCAE Version 5.0 and Electrodiagnostic tests including nerve conduction velocity, SNAP amplitude، SNAP latency

Secondary outcomes

1

Description

Quality of Life (QoL)

Timepoint

Before treatment, during treatment q3 weeks and after the end of treatment

Method of measurement

EORTC-QLQ-CIPN20 questionnaire

Intervention groups

1

Description

Intervention group: Prescription of coenzyme Q10 for the prevention and treatment of chemotherapy-induced neuropathy.

Category

Prevention

2

Description

Control group: Administration of a placebo, identical in appearance and quantity to the active drug, in the intervention group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

besat Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
Hamedan 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
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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
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