Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the effectiveness of melatonin for the prevention of taxane-induced peripheral neuropathy in patients with breast cancer: A double-blinded randomized clinical trial

Protocol summary

Study aim

Evaluating the efficacy of melatonin for the prevention of taxane-induced peripheral neuropathy

Design

In this phase 3 randomized double-blinded controlled clinical trial, 132 patients with breast cancer who are candidates for chemotherapy with taxanes will be divided into intervention (n = 66) and placebo (n = 66) groups based on a random number table.

Settings and conduct

Patients in melatonin group will receive 15 mg of melatonin daily from the first day of receiving docetaxel for 12 weeks. Likewise, patients in the control group will receive a placebo daily for 12 weeks. At baseline, patients will be assessed in terms of neuropathy via The Michigan Neuropathy Screening Instrument (MNSI), DN4 questionnaire, neurofilaments, and Diapazone test. Demographic characteristics, taxane-induced adverse effects, sleep quality, anxiety, and other medications will be recorded for each patient. Patients will be reassessed for neuropathy at the end of their chemotherapy and 3 months after chemotherapy termination. The study will be carried out in Shahid Ghazi hospital, Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of age 18-85 years with breast cancer who are candidates for chemotherapy with taxanes; exclusion criteria: history of neuropathy, use of medications that can cause neuropathy, history of allergy to melatonin, alcohol intake, active infection, history of prior chemotherapy, severe kidney or liver disease

Intervention groups

Patients in the first group (experimental group) will receive melatonin. The second group will be considered a placebo group and patients will receive a placebo.

Main outcome variables

Frequency of taxane-induced peripheral neuropathy

General information

Reason for update

I respectfully request an amendment to the start and end dates of the patient enrollment period for our registered trial. The initially recorded dates in the primary registration were estimated based on the research team's preliminary planning. However, following the finalization of study documentation and reports, the exact start and end dates have now been determined based on valid supporting documents, including the Ethics Committee approval letter and the dates of the first and last patient visits. Since the actual dates of the study differ from those previously entered in the system, and given that accurate timeline reporting is essential for the scientific validity of the study—particularly for international journals (otherwise, the study may be considered retrospective and face rejection during the peer-review process)—I kindly request that the system be updated with the correct dates, as supported by the attached documentation. I would be grateful for your guidance and consideration. Should any further documents or clarifications be required, I am ready to provide them promptly.

Acronym

METANE

IRCT registration information

IRCT registration number: **IRCT20160310026998N14**
Registration date: **2023-04-11, 1402/01/22**
Registration timing: **prospective**

Last update: **2026-08-04, 1405/05/13**
Update count: **1**

Registration date

2023-04-11, 1402/01/22

Registrant information

Name

Saba Ghaffary

Name of organization / entity
Faculty of Pharmacy, Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-03, 1402/01/14
Expected recruitment end date
2024-04-02, 1403/01/14
Actual recruitment start date
2023-12-04, 1402/09/13
Actual recruitment end date
2025-04-12, 1404/01/23
Trial completion date
2025-04-12, 1404/01/23

Scientific title
Evaluating the effectiveness of melatonin for the prevention of taxane-induced peripheral neuropathy in patients with breast cancer: A double-blinded randomized clinical trial

Public title
The efficacy of melatonin for the prevention of taxane-induced peripheral neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with breast cancer who are candidate for chemotherapy with taxanes
Exclusion criteria:
History of neuropathy Use of medications that can cause neuropathy such as statins, colchicine, zidovudine, penicillamine, platinum derivatives (cisplatin, oxaliplatin), and vinca alkaloids History of fibromyalgia, rheumatoid arthritis, osteoarthritis, hypothyroidism, sleep apnea, autoimmune diseases, diabetes mellitus, heart failure, myocardial infarction, uncontrolled hypertension, unstable angina, stroke, and seizure in the previous year History of allergy to melatonin Alcohol intake Active infection (such as COVID-19 or other respiratory infections) History of prior chemotherapy Severe kidney or liver failure Presence of other malignancies Prediction of patient nonadherence
Age
From **18 years** old to **85 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **132**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
132 patients with breast cancer who are candidates for chemotherapy with taxanes and referred to the clinic or hospital ward of Shahid Ghazi Hospital will be divided into two groups (intervention and control) after screening based on inclusion and exclusion criteria. A simple randomization procedure will be performed based on a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients with breast cancer who are qualified to participate in the study based on the inclusion and exclusion criteria will enter the study after signing informed consent. Participants will not be aware of the type of drug (either melatonin or placebo). Also, researcher and physicians who refer the patients to the researcher will not be informed about the type of drug (either melatonin or placebo). Only the monitoring committee of the clinical study is informed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee at Tabriz University of Medical Sciences
Street address
Shahid Ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2023-02-20, 1401/12/01
Ethics committee reference number
IR.TBZMED.REC.1401.1045

Health conditions studied

1

Description of health condition studied
Taxane-induced peripheral neuropathy in patients with breast cancer
ICD-10 code
D24.9
ICD-10 code description
benign neoplasm of breast

Primary outcomes

1

Description
Frequency of peripheral neuropathy
Timepoint
At baseline, after 12-week intervention, and 3 months after intervention termination
Method of measurement
The Michigan Neuropathy Screening Instrument (MNSI), DN4 questionnaire, neurofilaments and Diapazone test

Secondary outcomes

1

Description
Adverse effects of taxanes
Timepoint
At baseline, after the 12-week intervention, and 3 months after intervention termination
Method of measurement
The Functional Assessment of Cancer Therapy-Taxane (FACT-Taxane) questionnaire

2

Description
Anxiety in patients
Timepoint
At baseline, after 12-week intervention, and 3 months after intervention termination
Method of measurement
PROMIS Emotional Distress – Anxiety – Short Form

Intervention groups

1

Description
Intervention group: Patients will receive 15 mg of melatonin (3 tablets of melatonin 5 mg - JALINOUS Co.) daily at bedtime for 12 weeks. The first day of chemotherapy with taxanes will be the first day of melatonin use.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive placebo daily at bedtime for 12 weeks. The first day of chemotherapy with taxanes will be the first day of placebo use.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Ghazi Hospital in Tabriz, Iran
Full name of responsible person
Saba Ghaffary
Street address
Shahid Ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street
City
Tabriz
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Postal code
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Phone
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Fax
Email
saba_gh_64@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Saba Ghaffry
Street address
Central building of Tabriz University of Medical Sciences, Golgasht boulevard, Azadi street
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ghaffarys@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

saba Ghaffary

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Clinical pharmacy

Street address

Shahid Ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Saba Ghaffry

Position

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Person responsible for updating data

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Tabriz University of Medical Sciences

Full name of responsible person

Saba Ghaffary

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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