Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Acronym

METANE

IRCT registration information

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

Last update: **2023-04-11, 1402/01/22**
Update count: **0**

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)

Phone

+98 33266042

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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

empty

Actual recruitment end date

empty

Trial completion date

empty

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**

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
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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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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

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Person responsible for scientific inquiries

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Position
Assistant Professor of Clinical Pharmacy

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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
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