

# 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

##### Email address

ghaffarys@tbzmed.ac.ir

##### 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166616471

##### Phone

+98 41 3336 5010

##### Fax

##### Email

ghaffarys@tbzmed.ac.ir

## 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166616471

##### Phone

+98 41 3336 5010

##### Email

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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

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

**City**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor of Clinical Pharmacy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

Saba Ghaffary

**Position**

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**Latest degree**

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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