Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Double-Blind Evaluation of the Preventive Effect of Melatonin in Reducing the Severity of Paclitaxel-Induced Peripheral Neuropathy Compared to Placebo in Breast Cancer Patients .

Protocol summary

Study aim

Evaluation of the preventive effect of melatonin in reducing the severity of paclitaxel induced peripheral neuropathy compared with placebo in breast cancer patients receiving chemotherapy.

Design

Randomized double blind three arm parallel placebo controlled clinical trial with 80 participants. Allocation ratio 1:1:1 using permuted block randomization. Sequence generated by computer and concealed. Participants, clinicians, outcome assessors and data analysts are blinded.

Settings and conduct

The study will be conducted at Shahid Rajaei Hospital, Babolsar, Iran. Assessments will be performed at baseline, during chemotherapy cycles, and one month after completion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients aged 18 to 70 years with histologically confirmed breast cancer scheduled for ACT chemotherapy. ECOG performance status 0 to 2. Written informed consent required. Exclusion criteria: prior chemotherapy within 6 months, baseline neuropathy, major organ failure, other malignancies, alcohol abuse, pregnancy or breastfeeding.

Intervention groups

Group A1 melatonin 10 mg daily; Group A2 melatonin 20 mg daily; Group B placebo identical capsule. Treatment starts with paclitaxel and continues until one month after 12 weekly cycles

Main outcome variables

Severity of paclitaxel induced peripheral neuropathy assessed by EORTC QLQ CIPN20; nerve conduction study findings.

General information

Reason for update

Acronym

MELTAX Trial

IRCT registration information

IRCT registration number: **IRCT20241208063980N1**

Registration date: **2026-07-21, 1405/04/30**

Registration timing: **prospective**

Last update: **2026-07-21, 1405/04/30**

Update count: **0**

Registration date

2026-07-21, 1405/04/30

Registrant information

Name

Mina Heidarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 919 613 5200

Email address

hdn.mina721@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Double-Blind Evaluation of the Preventive Effect of Melatonin in Reducing the Severity of Paclitaxel-Induced Peripheral Neuropathy Compared to Placebo in Breast Cancer Patients .

Public title
Effect of Melatonin on the Prevention of Paclitaxel-Induced Neuropathy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Female patients with pathologically confirmed breast cancer Patients who are candidates for paclitaxel-containing chemotherapy regimen (ACT). Patients with an ECOG performance status of 0–2. Patients aged between 18 and 70 years Patients who provide written informed consent to participate in the study.

Exclusion criteria:
History of other malignancies Chemotherapy within the last 6 months Chronic use of multivitamins, magnesium, or calcium within the last month Cardiac, renal, or hepatic failure Baseline peripheral neuropathy Alcohol abuse or regular alcohol consumption Pregnancy or breastfeeding

Age
From **18 years** old to **70 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization and description: Permuted block randomization will be used to allocate participants into three study groups with a 1:1:1 allocation ratio. Unit of randomization: Individual patient (each participant will be randomized separately). Stratification: No stratified randomization will be applied in this study. Randomization tool and sequence generation: The random allocation sequence will be generated using computer-based statistical software by an independent statistician who is not involved in patient recruitment, treatment, or outcome assessment. Allocation concealment: Allocation concealment will be ensured through a centralized computer-generated randomization system. The allocation sequence will remain inaccessible to investigators until the time of assignment. Participants and outcome assessors will be blinded to group allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind. Participants will not be aware of their treatment allocation (melatonin 10 mg, melatonin 20 mg, or placebo). The study medications will be prepared as identical capsules with identical appearance and coded labeling. The treating clinicians and healthcare providers responsible for patient care will not be informed of group allocation. Outcome assessors who perform neuropathy evaluations (EORTC-QLQ-CIPN20 and EMG/NCS) will be blinded to treatment assignment. Data analysts will also remain blinded to group allocation until completion of the primary analysis. The randomization code will be kept confidential by an independent statistician and will not be disclosed until the end of the study. The principal investigator will not have access to the allocation code during the conduct of the trial.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Ganj Afrouz Street

City
Babolsar

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Approval date
2026-06-14, 1405/03/24

Ethics committee reference number
IR.MUBABOL.HRI.REC.1405.111

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Severity score of paclitaxel induced peripheral neuropathy assessed by the EORTC QLQ CIPN20 questionnaire.

Timepoint
Primary outcome will be assessed at baseline prior to initiation of paclitaxel chemotherapy, at the end of each weekly paclitaxel cycle during 12 treatment cycles, and one month after completion of the last paclitaxel cycle.

Method of measurement
Assessments will be performed at three time points: before initiation of chemotherapy, including completion of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Chemotherapy Induced Peripheral Neuropathy twenty item version, nerve conduction study and electromyography of the lower limbs, and completion of the food frequency questionnaire; at the end of each weekly paclitaxel cycle including completion of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Chemotherapy Induced Peripheral Neuropathy twenty item version and recording of treatment adherence and concomitant analgesic use; and one month after completion of treatment including repeat of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Chemotherapy Induced Peripheral Neuropathy twenty item version and nerve conduction study and electromyography

Secondary outcomes

1

Description
Need for analgesic medications during paclitaxel chemotherapy as an indicator of neuropathic symptom severity.

Timepoint
Measurement of the secondary outcome, including the need for analgesic medication, will be performed at baseline before initiation of chemotherapy, at the end of each weekly cycle of paclitaxel during twelve treatment cycles, and one month after completion of treatment.

Method of measurement
Need for analgesic medications during chemotherapy will be assessed using clinical documentation of analgesic consumption, including non steroidal anti inflammatory drugs and opioid medications, recorded in patient medical records and through patient reported daily drug use logs.

Intervention groups

1

Description
Intervention group1: Melatonin 10 mg oral capsule administered once daily at bedtime. Treatment will start from the first cycle of paclitaxel chemotherapy and continue daily until one month after completion of twelve weekly cycles.Intervention group 2: Melatonin 20 mg oral capsule administered once daily at bedtime. Treatment duration and schedule are identical to intervention group

Category
Prevention

2

Description
Control group: Placebo capsules identical in appearance to melatonin capsules, administered once daily at bedtime. Treatment duration and schedule are identical to intervention groups.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaei Hospital

Full name of responsible person
Mina Heidarian

Street address
Shahid Rajaei Hospital, Shariati Street, Babolsar, Mazandaran Province, Iran

City
Babolsar

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Phone
+98 11 3528 9260

Email
hdn.mina721@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr Reza Ghadimi

Street address
Shahid Rajaei Hospital, Shariati Street, Babolsar, Mazandaran Province, Iran

City
Babolsar

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Phone
+98 11 3528 9260

Email
hdn.mina721@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Mina Heidarian
Position
Radiation oncology resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Shahid Rajaei Hospital, Shariati Street, Babolsar, Mazandaran Province, Iran
City
Babolsar
Province
Mazandaran
Postal code
۴۷۱۷۶۴۷۷۴۵
Phone
+98 11 3528 9260
Email
hdn.mina721@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mina Heidarian
Position
Radition oncology resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Shahid Rajaei Hospital, Shariati Street, Babolsar, Mazandaran Province, Iran
City
Babolsar
Province
Mazandaran
Postal code
۴۷۱۷۶۴۷۷۴۵
Phone
+98 11 3528 9260
Email
hdn.mina721@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mina Heidarian
Position
Radiation oncology resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Shahid Rajaei Hospital, Shariati Street, Babolsar, Mazandaran Province, Iran
City
Babolsar
Province
Mazandaran
Postal code
۴۷۱۷۶۴۷۷۴۵
Phone
+98 11 3528 9260
Email
hdn.mina721@gmail.com

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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
The deidentified individual participant data, including baseline characteristics, outcome measures, and adverse

events; study protocol; statistical analysis plan; data dictionary.

When the data will become available and for how long

Access will be available from 6 months after publication of the primary study results.

To whom data/document is available

Qualified researchers from academic or research institutions for non commercial purposes.

Under which criteria data/document could be used

Data may be used only for non commercial academic research. Secondary analyses must preserve participant confidentiality and comply with ethical standards

From where data/document is obtainable

Requests should be sent to the principal investigator via institutional email

What processes are involved for a request to access data/document

Requests will be reviewed by the study team. Approved requests will receive de identified datasets after signing a data sharing agreement.

Comments