Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

The effect of melatonin on incidence and severity of arthralgia-myalgia caused by weekly paclitaxel in patients with breast cancer

Protocol summary

Study aim

1.Determine the course of arthralgia-myalgia during the whole treatment period (12 weeks) 2.Determination of the effect of melatonin on the severity of arthralgia-myalgia 3.Determination of the effect of melatonin on duration of arthralgia-myalgia 4.The effect of melatonin on the incidence of arthralgia-myalgia 5.The effect of melatonin on the prevention of peripheral neuropathy induced by paclitaxel 6.Determining the relationship between severity of arthralgia-myalgia and incidence of neuropathy 7.The relationship between arthralgia-myalgia severity and activity of daily living 8.Determination of the effect of melatonin on reducing the dosage of analgesic drugs

Design

Randomized, double-blinded, parallel, placebo-controlled clinical trial with 30 patients in each group.

Settings and conduct

This double blind study will be done in order to evaluation of prevention effects of Melatonin on arthralgia-myalgia and neurotoxicity by Brief Pain Inventory (BPI) and NCI-CTCAE and DN4 measurement . Researcher and patients are blind.

Participants/Inclusion and exclusion criteria

inclusion criteria: ≥ 18 years of age breast cancer patients who receive Paclitaxel with 80 mg/m2 of dose in one day and the chemotherapy courses are repeated every 1 weeks. exclusion criteria: metastatic breast cancer or the history of using other neurotoxic drugs.

Intervention groups

Intervention group: Melatonin with dose of 10 mg from Best naturals company will be prescribed every night from the day Paclitaxel administration to one week period. Control group: One tablet of Placebo will be prescribed every night from the day Paclitaxel administration to one week period.

Main outcome variables

arthralgia/ myalgia/ neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190630044057N1**
Registration date: **2019-09-28, 1398/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**
Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Naeeme Talaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4406 1922

Email address

ntalaee64@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on incidence and severity of arthralgia-myalgia caused by weekly paclitaxel in patients with breast cancer

Public title
Effect of Melatonin on arthralgia-myalgia of Paclitaxel
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women with Breast Cancer and Candidate receiving Paclitaxel 80 mg / m 2 weekly for 12 weeks after doxorubicin + cyclophosphamide regimen Age over 18 years Ability to take oral medication Ability to fill out a questionnaire Not taking pain relief medication for chronic No peripheral neuropathy No history of fibromyalgia, Rheumatoid arthritis, Osteoarthritis No history of receiving paclitaxel or any other drug with neurotoxicity Uncontrolled diabetes no history of receiving alcohol, statin, colchicine, zidovudine, penicillamine. no history of metastatic disease
Exclusion criteria:
Patients with concurrent GCSF administration Patients who experience trauma or falling during the study Viral Respiratory Infection During Study
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double blind clinical trial conducted at Cancer Institute Clinic. Patients fall into two groups using block randomization. One group received placebo with chemotherapy and the other received melatonin with chemotherapy.
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the institute of pharmaceutical sciences Tehran university of medical sciences
Street address
Tehran university of medical sciences
City
Tehran
Province
Tehran
Postal code
0
Approval date
2019-08-05, 1398/05/14
Ethics committee reference number
IR.TUMS.TIPS.REC.1398.043

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
Arthralgia
Timepoint
Arthralgia before Paclitaxel administration and daily after
Method of measurement
Brief Pain Inventory (BPI) and National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE)

2

Description
Myalgia
Timepoint
Myalgia before Paclitaxel administration and daily after
Method of measurement
Brief Pain Inventory (BPI) and National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE)

3

Description
neuropathy
Timepoint
neuropathy before Paclitaxel administration and weekly after
Method of measurement
Douleur Neuropathique 4 Questions (DN4) and National

Cancer Institute- Common Terminology Criteria for Adverse Events (NCI-CTCAE)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Melatonin with dose of 10 mg from Best naturals company will be prescribed every night from the day Paclitaxel administration to one week period for 12 weeks.
Category
Prevention

2

Description
Control group: One tablet of Placebo will be prescribed every night from the day Paclitaxel administration to one week period for 12 weeks.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
cancer institute of Imam Khomeini hospital
Full name of responsible person
Zahra Jahangard Rafsanjani
Street address
Keshavarz Ave., Imam Khomeini hospital
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1692
Email
ntalaee64@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zahra Jahangard-Rafsanjani
Street address
16 azar Ave, Keshavarz Ave,
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1692
Email
ntalaee64@gmail.com
Grant name
Research committee of Tehran university of medicalsciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zahra Jahangard-Rafsanjani
Position
Aššistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Keshavarz Ave
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1692
Email
zjahangard@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Zahra Jahangard-Rafsanjani
Position
Aššistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Keshavarz Ave
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1692
Email
zjahangard@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Naeeme Talaee
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No.43, Khanbabaee Ave.,Ayatollah Kashani Blvd.,
City
Tehran
Province
Tehran
Postal code
1481877416
Phone
+98 21 4406 1922
Email
ntalaee64@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data like patient inventory data and effects of Melatonin and side effects of chemotherapy will be published in form of article
When the data will become available and for how long
At the end of study and after publication
To whom data/document is available
Scientific researchers
Under which criteria data/document could be used
For more researches
From where data/document is obtainable
Zahra Jahangard-Rafsanjani
What processes are involved for a request to access data/document
After acceptance by Zahra Jahangard-Rafsanjani
Comments