

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 / m² 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	

<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Breast cancer
ICD-10 code	C50
ICD-10 code description	Malignant neoplasm of breast
Primary outcomes	
<u>1</u>	
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)
<u>2</u>	
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)
<u>3</u>	
Description	neuropathy
Timepoint	neuropathy before Paclitaxel administration and weekly after
Method of measurement	Douleur Neuropathique 4 Questions (DN4) and National

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

ntalae64@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

ntalae64@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

Assistant 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

Assistant 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

Postal code

1481877416

Phone

+98 21 4406 1922

Email

ntalae64@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**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, Khanabaaee Ave., Ayatollah Kashani Blvd.,

City

Tehran

Province

Tehran