Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison evaluation of sleep disorders incidence in patients with primary breast cancer admitted to Imam Khomeini hospital in Tehran received melatonin during adjuvant chemotherapy

Protocol summary

Study aim

Determination of the incidence of sleep disorders in patients with primary breast cancer referring to Imam Khomeini Hospital in Tehran under chemotherapy for adjuvant and melatonin

Design

120 patients are randomly placed in blocks of 6. In each block, 3 patients receive melatonin and 3 patients receive placebo. The randomization is done by Dr. Jahangard and only she knows the type of drug prescribed to each patient.The encoded drug packs will be placed at the outpatient chemotherapy pharmacy located at the Cancer Institute, and will be delivered to the patient in accordance with the code given to each patient.

Settings and conduct

This study was designed in double blind clinical trial. The 120 breast cancer patients in stages of one to three, whose breast surgery was done for them in last 3 months, will enroll in this study at the Cancer Institute of Tehran Imam Khomeini Hospital. These participants will randomly placed in two melatonin and placebo groups. Each group consists of 60 patients. The patients in melatonin group will receive 6 mg melatonin (2 tablets) before sleep. At first, with psychiatric interview patients with sleep disorders, depression and anxiety need medication are excluded. Two groups at three times (before, after fourth cycle and at the end of chemotherapy) are assessed for sleep quality with the Pittsburgh Sleep Quality Index. Chemotherapy will be the same in both groups as dose dense protocol (cyclophosphamide 600 mg/m² & adriamycin 60 mg/m² each 2 weeks for 4 cycles, then docetaxel 100 mg/m² with each 3 weeks for 4 cycles). Trastuzumab 6 mg/kg in HER2 positive patients will add to docetaxel. Leukopenia and thrombocytopenia will check before each cycle of chemotherapy administration. At the end, sleep quality and myelosuppression in the two groups were compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria (all of them required): 1- Patients who are in stage one to three breast cancer and cancer surgery is performed within the last three months. 2- No history of prior chemotherapy 3- No contraindication for adjuvant chemotherapy of breast cancer (including heart failure and drug hypersensitivity) 4- 40 to 60 years old at the onset of chemotherapy 5- The absence of uncontrolled diabetes and renal failure with glomerular filtration less than 30 Exclusion criteria: 1- Delay or discontinuation of chemotherapy over one month for any reason 2- Sleep disorder, depression and anxiety requiring drug treatment.

Intervention groups

group that receives melatonin at the same time as chemotherapy.

Main outcome variables

Score in Pittsburgh Sleep Disorder Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150726023349N4**
Registration date: **2018-02-15, 1396/11/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-15, 1396/11/26**
Update count: **0**

Registration date

2018-02-15, 1396/11/26

Registrant information

Name

Mohsen Esfandbod

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2018-09-23, 1397/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison evaluation of sleep disorders incidence in patients with primary breast cancer admitted to Imam Khomeini hospital in Tehran received melatonin during adjuvant chemotherapy

Public title
Effect of melatonin on sleep quality in breast cancer patients during chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are in stage one to three breast cancer and cancer surgery is performed within the last three months. No history of prior chemotherapy No contraindication for adjuvant chemotherapy of breast cancer (including heart failure and drug hypersensitivity) 40 to 60 years old at the onset of chemotherapy The absence of uncontrolled diabetes and renal failure with glomerular filtration less than 30
Exclusion criteria:
Delay or discontinuation of chemotherapy over one month for any reason Sleep disorder, depression and anxiety requiring drug treatment
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly placed in blocks of 6. In each block, 3 patients receive melatonin and 3 patients receive placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
The randomization is done by Dr. Jahangard and only she knows the type of drug prescribed to each patient.The encoded drug packs will be placed at the outpatient chemotherapy pharmacy located at the Cancer Institute, and will be delivered to the patient in accordance with the code given to each patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Keshavarz Boulevard, Cornre of the Ghods Street, Central Organization of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-06-12, 1396/03/22
Ethics committee reference number
IR.TUMS.IKHC.REC.1396.3606

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50.9
ICD-10 code description
Malignant neoplasm: Breast, unspecified

Primary outcomes

1

Description
Sleep quality
Timepoint
Before start of chemothrapy, after forth cycle and at of the chemothrapy
Method of measurement
Pittsburgh sleep quality index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 120 patients with breast cancer stage one to three who have undergone cancer surgery in the last three months are enrolled to receive standard adjuvant chemotherapy. Of the 120 patients, 60 were randomly selected and placed in the intervention group. At first, psychiatric interview will be perform to exclude patients with sleep disorders, depression and anxiety required drug administration. Patients will be evaluate with Pittsburgh questionnaire three times (before, after the fourth turn, and at the end of chemotherapy) to assess sleep quality.Chemotherapy will be administered according to the dose dense protocol, cyclophosphamide dosage of 600 mg per body surface, and adriamycin 60 mg per body surface area every four weeks for four times, followed by 80 mg / kg body weight per week for 12 times. It is worth noting that trastuzumab will be prescribed if HER2 is positive in immunohistochemical staining and in the absence of a cardiac prohibition. In the first injection 8 mg per body weight, and at a subsequent dose of 6 mg per body weight, every 3 weeks, trastuzumab will be infused. In the case of platelets less than 100,000, or white blood cells less than 2000 per micro-liter at the time of chemotherapy, that chemotherapy session will be delayed until cytopenia improve to the extent indicated.Intervention in this group is given as two 3 mg melatonin tablets (N-Acetyl-5-methoxytryptamine), manufactured by Razak Laboratories, each night at 8 pm during chemotherapy for 6 months.Possible side effects of melatonin include: 1- Sensitization reaction (shortness of breath, skin rash) 2- Daytime sleepiness 3 - Nightmare 4 - Headache. The following measures are recommended when complications occur: 1- Discontinue the medication and see a physician as soon as possible. 2- If severe signs of allergy occur, take one tablet of loratadine and go to the emergency department.
Category
Treatment - Drugs

2

Description
Control group: 120 patients with breast cancer stage one to three who have undergone cancer surgery in the last three months are enrolled to receive standard adjuvant chemotherapy. Of the 120 patients, 60 were randomly selected and placed in the intervention group, and 60 others were randomly assigned to the control group. Like the intervention group, at first, psychiatric interview will be perform to exclude patients with sleep disorders, depression and anxiety required drug administration. Patients will be evaluated with Pittsburgh questionnaire three times (before, after the fourth turn, and at the end of chemotherapy) to assess sleep quality. Chemotherapy will be administered according to the dose dense protocol, cyclophosphamide dosage of 600 mg per body surface, and adriamycin 60 mg per body surface area every four weeks for four times, followed by 80 mg / kg body weight per week for 12 times. It is worth noting that trastuzumab will be prescribed if HER2 is positive in immunohistochemical staining and in the absence of a cardiac prohibition. In the first injection 8 mg per body weight, and at a subsequent dose of 6 mg per body weight, every 3 weeks, trastuzumab will be infused. In the case of platelets less than 100,000, or white blood cells less than 2000 per micro-liter at the time of chemotherapy, that chemotherapy session will be delayed until cytopenia improve to the extent indicated.In this group, during chemotherapy for 6 months patients are given 2 placebo tablets with the same appearance as melatonin tablets take the intervention group, every night at 8 pm. Placebo tablets are also produced by Razak Laboratories.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Institude of Imam Khomeini Hospital Complex
Full name of responsible person
Dr Mohsen SeddighShamsi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences

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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
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
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Dr Mohsen Seddigh Shamsi
Position
Internist
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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