Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of concurrent administration of melatonin and neoadjuvant Chemotherapy on the pathological response in breast cancer patients

Protocol summary

Study aim

The effect of concurrent administration of melatonin and neoadjuvant chemotherapy on the pathological response in breast cancer patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 52 patients. Randomization will be done using STATA software and using random blocks.

Settings and conduct

Fifty-two patients with non-metastatic breast cancer who are candidates for neoadjuvant chemotherapy in Imam Reza and Ghaem hospitals are randomly divided into two intervention and control groups (26 people in each group). Chemotherapy is performed similarly in the two groups. The pathological response after surgery is compared in two groups.

Participants/Inclusion and exclusion criteria

1-Patients with stage one to three breast cancers 2- No previous history of chemotherapy 3-Absence of contraindications to neoadjuvant chemotherapy for breast cancer (including heart failure and drug allergies) 4- Age 30 to 60 years at the time of starting chemotherapy 5-Absence of uncontrolled diabetes, renal failure with glomerular filtration less than 30 and liver failure

Intervention groups

Intervention group: Patients are prescribed a 10 mg tablet of melatonin at bedtime during a 5-month course of chemotherapy. control group: Patients in the control group are given one placebo tablet (similar to melatonin tablets) each night during a 5-month course of chemotherapy.

Main outcome variables

The pathological response after neoadjuvant chemotherapy is assessed according to the Chevallier system as follows: 1- Pathological complete response: Disappearance of all the tumor cells in breast and lymph nodes 2- Pathological partial response: Presence of invasive carcinoma with stromal alterations 3- Pathological no response: little modification in the original tumor appearance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200409047007N3**
Registration date: **2021-12-02, 1400/09/11**
Registration timing: **prospective**

Last update: **2021-12-02, 1400/09/11**
Update count: **0**

Registration date

2021-12-02, 1400/09/11

Registrant information

Name

Mohsen Seddigh-Shamsi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 8818

Email address

seddighshamsim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of concurrent administration of melatonin and neoadjuvant Chemotherapy on the pathological response in breast cancer patients

Public title

The effect of concurrent administration of melatonin and neoadjuvant Chemotherapy on the pathological response in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with stage one to three breast cancers Age 30 to 60 years at the time of starting chemotherapy

Exclusion criteria:

No previous history of chemotherapy Absence of contraindications to neoadjuvant chemotherapy for breast cancer including heart failure and drug sensitivity Absence of uncontrolled diabetes, renal failure with glomerular filtration less than 30 and liver failure

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

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 and patients are placed in blocks in the order of enrollment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization was performed by Dr. Fazelipour and only she knows the type of medicine that is prescribed to each patient. The coded drug packages will be placed in the pharmacy next to the chemotherapy ward and will be delivered to each patient according to the code given to him. Patients, planners, physicians, and those who analyze the data are unaware of the type of medication each patient is receiving.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central University Building, University Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.252

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

Pathological response

Timepoint

surgery after neoadjuvant chemotherapy

Method of measurement

The pathological response after neoadjuvant chemotherapy is assessed according to the Chevallier system as follows:1- Pathological complete response: Disappearance of all the tumor cells in breast and lymph nodes2- Pathological partial response: Presence of invasive carcinoma with stromal alterations3- Pathological no response: little modification in the original tumor appearance.

Secondary outcomes

1

Description
Quality of life
Timepoint
At beginning and end of chemotherapy
Method of measurement
EORTC QLQ – BR23 questionnaire

Intervention groups

1

Description
Intervention group: Patients are prescribed a 10 mg tablet of melatonin at bedtime during a 5-month course of chemotherapy.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group are given one placebo tablet (similar to melatonin tablets) each night during a 5-month course of chemotherapy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr Afshin Imani
Street address
Department of Internal Medicine, Imam Reza Hospital, Shariati Square
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2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Street address
Deputy of Research and Technology, Central University Building, next to Hoveyzeh Cinema, University Street.
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GhayourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Seddigh Shamsi
Position
Associate professor
Latest degree

Subspecialist

Other areas of specialty/work

Hematology Oncology

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Email

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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

Undecided - It is not yet known if there will be 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

After collecting and analyzing the data, the results will be made available to the public in the form of articles.

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Physicians

Under which criteria data/document could be used

There are no restrictions

From where data/document is obtainable

Dr Mohsen Seddigh Shamsi, Mashhad University of Medical Science

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

Refer to the project supervisor

Comments