Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Melatonin in the management of menopausal complication, mood and sleep changes due to hormonal therapy in breast cancer patients

Protocol summary

Study aim

1) Determination and comparison of the mean number of hot flash during a day between intervention and placebo group 2) Determination and comparison of the severity of hot flash during a day between intervention and placebo group 3) Determination and comparison of the Menopause Rating Scale (MRS) criteria during a day between intervention and placebo group 4) Determination and comparison of the Sexual functional criteria during a day between intervention and placebo group 5) Determination and comparison of the Pittsburgh Sleep Quality Index (PSQI) during a day between intervention and placebo group

Design

Two arms randomised blind trial

Settings and conduct

This study will be conducted in Seyedoshohada hospital. The enrolled patients will receive melatonin or identical placebo with dose of 6 mg daily for 4 weeks prepared by Razak company.

Participants/Inclusion and exclusion criteria

Adult women suffering from hormone-positive breast cancer with grade I to III who are receiving Selective estrogen receptor modulators (SERM) or Aromatase inhibitors (AIs) family drug and complaining of hot flash at least four times a week will be included. Those who are taking any drugs with the potential of central nervous system suppression such as anti-psychotic, antidepressant, anti-anxiolytic and anti-epileptic will be excluded.

Intervention groups

All patients who were considered as inclusion criteria, after signing the consent will be administrated randomly by whether melatonin or identical placebo with 3 mg twice a day for 4 weeks. Patients' information will be completed according to study's endpoints by data gathering sheet or standard and a valid questionnaire including Menopause Rating Scale (MRS), Daily menopause diary, Female Sexual Function Index (FSFI), The Pittsburgh Sleep Quality Index at the baseline or 4 weeks after intervention.

Main outcome variables

hot flashes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040556N3**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **prospective**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name

Azadeh Moghaddas

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-19, 1399/02/30

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Melatonin in the management of menopausal complication, mood and sleep changes due to hormonal therapy in breast cancer patients

Public title
Melatonin in the management of breast cancer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult women suffering from hormone-positive breast cancer with grade I to III who are receiving Selective estrogen receptor modulators (SERM) or Aromatase inhibitors (AIs) family drug. Patients who are complaining from hot flash (at least 4 times in a previous month) Patients who have compliance and ability to take melatonin orally
Exclusion criteria:
Patients who are in metastatic stage Patients who have a history of other malignancies except for breast cancer Patients who are receiving antipsychotic, anti-depression, anti-anxiolytic, sedative or hypnotic or anti-epileptic drugs Patients with a history of hypersensitivity reaction to melatonin
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by Blocked randomization method. Information such as the number of intervention groups (two main intervention groups, for example, A and control, for example, B), block size (multiple numbers of groups, in this study to reduce complexity, 4 will be selected). The total number of patients (sample size 60) will be entered into Internet-specific software for this calculation (for example, available at " the Create a blocked randomisation list | Sealed Envelope"). For each included patients, a specific code will be allocated in order to determine the type of included group. The predicted sample size of patients will be accomplished randomly by using this method. The main investigator will allocate the concealed code to control group or case group according to random numbers and will put them to investigators who are in charge of sampling.
Blinding (investigator's opinion)
Double blinded
Blinding description
For keeping participants, investigator and health care providers blind, whole melatonin tablets will be extracted from blister and separated in 60-tablets considered packages by the main investigator. Finally, all drugs and placebo packages will be labelled by codes extracted from internet-based software. After completion of recruitment, each patients code were coordinated with software data and investigator or health care providers will be informed after data analyses of drugs' codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Faculty of Pharmacy, Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2020-03-04, 1398/12/14
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.724

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
The amount and severity of hot flash
Timepoint

Before intervention and 4 weeks

Method of measurement

Menopause Rating Scale (MRS) questionnaire

Secondary outcomes

1

Description

Sexual function

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Female Sexual Function Index questionnaire

Intervention groups

1

Description

Intervention group: Administration of 3 mg tablet of melatonin provided by Razak pharmaceutical Company, 6 mg daily (twice a day orally) for 4 weeks and then baseline and 4-weeks follow-up demographic data and questionnaire according to studies endpoints.

Category

Treatment - Drugs

2

Description

Control group: Administration of identical placebo tablet similar to melatonin tablet which have been provided by Razak pharmaceutical Company twice a day orally for 4 weeks and then baseline and 4-weeks follow-up demographic data and questionnaire according to studies endpoints.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohada Teaching Hospital

Full name of responsible person

Azadeh Moghaddas

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Faculty of Pharmacy, Isfahan University of Medical Sciences, Hezar Jarib, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou

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Grant name

Vice-Chancellery for Research of Isfahan University of Medical Sciences

Grant code / Reference number

50270

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Azadeh Moghaddas

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
All collected data
When the data will become available and for how long
From the summer of 2021
To whom data/document is available
All academic centres
Under which criteria data/document could be used
All documents with citation
From where data/document is obtainable
E-mail address
What processes are involved for a request to access data/document
After sending a request, we will call the related person and the data will be revealed in less than one week.
Comments