Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The evaluation of relationship between IL6(Interleukin-6) serum level and fatigue induced by adjuvant radiotherapy and chemotherapy in women with breast cancer treated with Melatonin drug: A clinical trial

Protocol summary

Study aim
Evaluation of relationship between IL6 serum level and fatigue induced by adjuvant radiotherapy and chemotherapy in breast cancer patients treated with Melatonin drug

Design
Phase 3 clinical trial with 64 patients with control group, community-based and pragmatic, with parallel groups, triple blinded, with a randomized block design

Settings and conduct
Female breast cancer patients with stages I to III who during the second half of 1397 will be referred to Mahdieh Hospital and Besat Hospital for receiving adjuvant radiation therapy and chemotherapy, using a simple randomization method, and with a full explanation of the study and Written consent will be entered into the study. With a randomized block design patients will be treated with Melatonin or placebo(control group). For blinding medicine and placebo are put in similar envelopes in the opaque package, which have been numbered. Blocking and preparation of envelopes is done by a non-involved person in data sampling and analysis, and thus the health care provider, the data collector, the participant and the person analyzing the data, are not aware of the intervention type received, and Who is located in each group

Participants/Inclusion and exclusion criteria
Female breast cancer patients with stage I-III(according to the AJCC) who receive adjuvant chemotherapy and radiation therapy; No Consumption of Warfarin, Methylphenidate and Hypnotics during using Melatonin, No Pregnancy or Breastfeeding

Intervention groups
Patients will be randomly treated with melatonin or placebo(control group). Oral Melatonin Drug 6 mg(2 mg capsule 3 mg) from 3 to 7 days before the start of Adjuvant treatment will be consumed every night until the disease progression

Main outcome variables
IL6 serum level; Type of treatment; Gender; Age; Fatigue severity; The type of adjuvant treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180426039421N2**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **prospective**

Last update: **2018-09-22, 1397/06/31**
Update count: **0**

Registration date
2018-09-22, 1397/06/31

Registrant information

Name
Zahra Kesht pour amlashi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 1076

Email address
z.keshtpour@edu.umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of relationship between IL6(Interleukin-6) serum level and fatigue induced by adjuvant radiotherapy and chemotherapy in women with breast cancer treated with Melatonin drug: A clinical trial

Public title

Relationship between IL6 and fatigue induced by radiotherapy and chemotherapy in patients treated with Melatonin drug

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Breast Cancer Stages I, II, III According to Pathological Reports Patients at least 18 Years Old Have Signed a Written Consent Recevieng Adjuvant Chemotherapy and Radiotherapy No Untreated Hypercalcemia No Systolic Blood Pressure Less Than 100 mm Hg No Warfarin Consumption No Methylphenidate Consumption No Sleep Pills During Melatonin Use No TSH>5/5 or <0/5 No Pregnancy or Breastfeeding

Exclusion criteria:

Expired During Treatment Stop Using Melatonin during Treatment

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Any number of female breast cancer patients with stage I-III(according to the AJCC system) are selected by simple randomization method and the patients are randomized(randomized block design) to receive Melatonin or placebo (control group)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding includes: Participants(patients) Clinical care provider(Radiation oncology physicians and chemotherapy nurses) Researcher and evaluator of the outcome and data analyzer: (Radiation oncology resident) In order to hide allocation, medicine and placebo are put in similar envelopes in the opaque package, which have been numbered. Blocking and preparation of envelopes are performed by a non-involved person in data sampling and analysis. Thus, the clinical care provider, the data collector, the participant and the data analyst, are unaware of the type of intervention received and who is located in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh Street, Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.UMSHA.REC.1397.298

Health conditions studied

1

Description of health condition studied

Breast Cance; Cancer Related Fatigue; Melatonin; Interleukin 6

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Fatigue severity in the BFI questionnaire

Timepoint

4 weeks after last adjuvant treatment session

Method of measurement

Brief Fatigue Inventory(BFI) questionnaire

2

Description
IL6(interleukin 6) serum level
Timepoint
4 weeks after last adjuvant treatment session
Method of measurement
Solid phase sandwich ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral Melatonin drug 6 mg(2 capsule of 3 mg) every night from 3 to 7 days before the start of Adjuvant treatmentwill be used until the disease progresses
Category
Rehabilitation

2

Description
Control group: The placebo will be taken every night from 3 to 7 days before the start of the adjuvant treatment until the disease progresses
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Diagnostic and Treatment Center
Full name of responsible person
Abdulazim Sedighi Pashaki
Street address
Mahdieh Diagnostic and Treatment Center, Parastar Ave., Besat Blvd.
City
Hamedan
Province
Hamadan
Postal code
8138381225
Phone
+98 81 3838 0044
Email
hmmahdiyeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad Haghighi
Street address
Hamedan University of Medical Sciences, Shahid Fahmideh Street, Hamedan
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3252 0183
Email
ICT@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Kesht pour amlashi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
MRI and Radiotherapy Center of Mahdie, Parastar Ave, Besat Blvd
City
Hamadan
Province
Hamadan
Postal code
8138381225
Phone
+98 81 3838 1076
Fax
Email

Zahraka@mail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Zahra Kesht Pour Amlashi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

Street address
MRI and Radiotherapy Center of Mahdie, Parastar Ave., Besat Blvd.

City
Hamadan

Province
Hamadan

Postal code
8138381225

Phone
+98 81 3838 1076

Email
z.keshtpour@edu.umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Zahra Kesht Pour Amlashi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

Street address
MRI and Radiotherapy Center of Mahdie, Parastar Ave., Besat Blvd.

City
Hamadan

Province
Hamadan

Postal code
8138381225

Phone
+98 81 3838 1076

Email
z.keshtpour@edu.umsha.ac.ir

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