

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Melatonin in treatment of menopausal like problems, mood and sleep chaging caused by androgen deprivation therapy in prostate cancer patients

Protocol summary

Study aim

Evaluation of the effect of Melatonin in treatment of menopausal like problems, mood and sleep chaging caused by androgen deprivation therapy in prostate cancer patients

Design

Two arms, parallel, controlled, blind, randomized clinical trial, phase 3, 66 patients. Randomization using permuted blocks method.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Adult men with prostate cancer who are being treated for androgen deprivation and complain of hot flashes at least 4 times a week are included in the study and patients who are taking any central nervous system suppressant such as antipsychotics, antianxiety, antidepressants or anticonvulsants are excluded.

Intervention groups

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. 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.

Main outcome variables

hot flashes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040556N5**

Registration date: **2020-08-27, 1399/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-27, 1399/06/06**

Update count: **0**

Registration date

2020-08-27, 1399/06/06

Registrant information

Name

Azadeh Moghaddas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 7074

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-18, 1399/02/29

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Melatonin in treatment of menopausal like problems, mood and sleep chaging caused by androgen deprivation therapy in prostate cancer patients

Public title

Evaluation of the effect of melatonin in the treatment of problems caused by androgen deprivation therapy in prostate cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All adult men (18 years and older) with prostate cancer treated with androgen deprivation therapy (ADT)
Patients with controlled hypertension
Patients who complain from menopausal complications such as hot flashes (at least 4 times a week in the past month)
Patient who has sufficient compliance and ability to take melatonin orally

Exclusion criteria:

Patients in the metastatic stage of prostate cancer
Patients with a history of other malignancies except prostate cancer
Concomitant treatment with progesterone agents or other treatments related to hot flashes
Concomitant treatment with chemotherapy, radiotherapy or surgery in the future
Patients receiving drugs such as propranolol (due to the relative effect on the central nervous system) and warfarin (due to the high risk of drug interactions)
No history of liver and kidney disorder or advanced heart failure
Patients with a history of allergy to melatonin-containing products
Recent use of SSRIs, SNRIs, antiepileptic drugs, and monoamine oxidase inhibitors
Patients taking sedative drugs such as benzodiazepines or non-benzodiazepines (such as zolpidem) regularly due to sleep problems

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is 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 is selected). The total number of patients (sample size 66) is 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 is allocated in order to determine the type of included group. The predicted sample size of patients are accomplished randomly by using this method. The main investigator allocates the concealed code to control group or case group according to random numbers and puts 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

Isfahan

Postal code

81746-73461

Approval date

2020-04-15, 1399/01/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.143

Health conditions studied

1

Description of health condition studied

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Email

azadeh_moghaddas@yahoo.com

Primary outcomes

1

Description

The amount and severity of hot flash

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Hot Flash Diary and Hot Flash Related Daily Interference

Scale questionnaire

Secondary outcomes

empty

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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Motahari Street, Isfahan Province, Isfahan, Iran

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8174673461

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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

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

Yes

Title of funding source

Esfahan 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

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