

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

moghaddas@pharm.mui.ac.ir

##### 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 changing 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

## 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

##### Street address

Motahari Street, Isfahan Province, Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3235 0210

#### Email

azadeh\_moghaddas@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjou

##### Street address

Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 7074

##### Email

azadeh\_moghaddas@yahoo.com

#### 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

##### Street address

Faculty of Pharmacy, Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran

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## Person responsible for scientific 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

**Street address**

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## Person responsible for updating data

**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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**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**

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**