Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Oct 2022

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

Protocol summary

Study aim
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

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
IRT registration number: IRCT201807222040556N5
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
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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 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 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 analyst
- 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
81764-73461

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
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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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Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran
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Grant name
Vice-Chancellery for Research of Isfahan University of Medical Sciences

Grant code / Reference number
Yes

Title of funding source
Vice-Chancellery for Research of 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
Latest degree
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Other areas of specialty/work
Others
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Other areas of specialty/work
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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