Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

investigation of effectiveness and non effectiveness of melatonin in sleep quality in patients with

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of melatonin on sleep quality in patients with cancer. This study is a not blinded clinical trial. The study population included patients with cancer who referred to Imam Reza Hospital in Kermanshah city. 44 patients in available method will be selected and will be assigned in the intervention group. Before the intervention, the Pittsburgh Sleep quality questionnaire will be completed in all patients. Then the patients of the study will receive 3 mg of melatonin daily for 1 month. Patients will be visited every week. At the end of the study the Pittsburgh Sleep quality questionnaire will be completed and the complications and problems associated with sleep medications will be compared with the initial results. Inclusion criteria: age between 16 to 80; Cancer patients who have trouble sleeping and chemotherapy have done for them and ended Exclusion criteria: patients with underlying disorders and uncontrolled medical problems such as diabetes; hypertension; seizures; addiction

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051027840N1**
Registration date: **2016-06-30, 1395/04/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-06-30, 1395/04/10

Registrant information

Name

Sepideh Tanhaie

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigation of effectiveness and non effectiveness of melatonin in sleep quality in patients with

Public title

investigation of melatonin in sleep quality in patients with cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 16 to 80; Cancer patients who have trouble sleeping and chemotherapy have done for them and ended Exclusion criteria: patients with underlying disorders and uncontrolled medical problems such as diabetes, hypertension, seizures; addiction and continuous use of sleep medications and anticoagulants

and anticonvulsants; Individuals treated with anticoagulants and anticonvulsants and antidepressants and sleeping drugs

Age
From **16 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2015-11-24, 1394/09/03

Ethics committee reference number
KUMS.REC.1394.186

Health conditions studied

1

Description of health condition studied
sleep quality disorders

ICD-10 code
G47

ICD-10 code description
sleep disorders

Primary outcomes

1

Description
Sleep quality

Timepoint
Baseline,once a week for a amonth

Method of measurement
Based on pittsburgh sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group will receive 3 mg of melatonin daily for 1 month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Sepideh Tanhaie

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person
Koroush Hamzehee

Street address
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Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Kermanshah University of

Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty