Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of the effect of melatonin and zolpidem in improving quality of sleep, anxiety and depression in colorectal cancer patients receiving chemotherapy

Protocol summary

Summary

This study is a randomized, double blind clinical trial that will be done on 90 colorectal cancer patients who have sleep disorder based on Pittsburgh Sleep Quality Questionnaire and are receiving chemotherapy regimen. After obtaining ethical approval and written informed consent form the patients, the two groups will be selected based on simple random blocks. Group A will receive melatonin 6 mg at night and the other group receives 10 mg zolpidem. In this double-blind trial, neither the participants nor the researchers know which participants belong to the melatonin group, nor the zolpidem group. To assess sleep quality of patients, Pittsburgh Sleep Quality Criteria at baseline and after 4 and 8 weeks of treatment will be used, Groningen Sleep Quality Scale Questionnaire will be used at baseline and after 2, 4 and 8 weeks of treatment. To provide an indication of depression and anxiety, and as a guide to evaluate recovery, the Hamilton Rating Scale for Depression and Anxiety will be used at baseline and after 2, 4 and 8 weeks of treatment. Questionnaires will be completed under the supervision of a specialist in clinical psychology and the data extraction and analysis performed by a statistician.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602147202N10**
Registration date: **2017-09-10, 1396/06/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-10, 1396/06/19

Registrant information

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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pghaeli@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of medical science

Expected recruitment start date

2017-03-18, 1395/12/28

Expected recruitment end date

2017-08-19, 1396/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of melatonin and zolpidem in improving quality of sleep, anxiety and depression in colorectal cancer patients receiving chemotherapy

Public title

Comparison Between Melatonin and Zolpidem in Improving Sleep quality, Anxiety and Depression

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age more than 18 colorectal cancer receiving chemotherapy regimen sleep disorder based on pitsburg questionnaire exclusion criteria: patients receiving hypnotics, antidepressants or anxiolytic medicines pregnancy lactation

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of medical Science

Street address
16 Azar street, Enghelab square

City
Tehran

Postal code

Approval date
2017-03-11, 1395/12/21

Ethics committee reference number
IR.TUMS.VCR.REC.1395.1911

Health conditions studied

1

Description of health condition studied
sleep disorder

ICD-10 code
G47.0

ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
sleep quality

Timepoint
At baseline, 1 month after the baseline and 2 months after baseline

Method of measurement
Pittsburgh Questionnaire

2

Description
sleep quality

Timepoint
At baseline, 2 weeks and 1 month after the baseline and 2 months after baseline

Method of measurement
GSQS Questionnaire

Secondary outcomes

1

Description
depression

Timepoint
At baseline, 2 weeks and 1 month after the baseline and 2 months after baseline

Method of measurement
Hamilton Rating Scale for Depression

Intervention groups

1

Description
intervention: 6 mg melatonin every night for 30 days

Category
Treatment - Drugs

2

Description
control: 10 mg zolpidem at night for 30 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Oncology ward, Sina hospital

Full name of responsible person
Ms. Ozlati

Street address
Hasan Abad squre

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Padideh Ghaeli

Street address

Tehran University of Medical Sciences, 16 Azar street, Enghelab square

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Tehran

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, Tehran 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

Contact

Name of organization / entity

tehran university of science

Full name of responsible person

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Position

Professor

Other areas of specialty/work

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shahrokhi.mail85@yahoo.com

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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