

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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

+98 21 6695 4709

##### Email address

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 pittsburg 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 square

##### **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

**City**

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**

dr. Padideh Ghaeli

**Position**

Professor

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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professor assistance

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

resident

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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*