

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of melatonin efficacy in prophylaxis of Oxaliplatin induced acute peripheral neuropathy in FOLFOX regimen in patients with colon cancer

#### Protocol summary

##### Study aim

1- Investigating the effect of melatonin in reducing the incidence of oxaliplatin acute neuropathy in colon cancer patients receiving FOLFOX 2- Investigating the effect of melatonin in reducing the severity of oxaliplatin acute neuropathy 3- Investigating the effect of melatonin in reducing the duration of oxaliplatin acute neuropathy

##### Design

Randomised, superiority, parallel group trial with blinded outcome assessment phase 3 in 70 cases and control ( 35 patients in each group).

##### Settings and conduct

Using the block randomization method, patients are randomly assigned to two groups of 35 people receiving chemotherapy regimen with placebo or the chemotherapy regimen group with melatonin. One group of patients with colon cancer receiving FOLFOX chemotherapy regimens containing oxaliplatin at a dose of 85 mg/m<sup>2</sup> every 2 weeks before the start of chemotherapy will be given 10 mg melatonin tablets daily and another group with the same number of patients will be given placebo daily. and a three-month follow-up of acute neuropathy will be done. In order to check the patient's acceptance of the drug, pills are provided to the patients in each period of chemotherapy treatment.

##### Participants/Inclusion and exclusion criteria

All patients with history of DM or any type of peripheral nerve injury

##### Intervention groups

Colon cancer patients under FOLFOX chemotherapy regimen containing oxaliplatin, has been given placebo in the control group and melatonin in intervention group

##### Main outcome variables

Reducing the incidence of oxaliplatin acute neuropathy ;  
Reducing the severity of oxaliplatin acute neuropathy ;  
Reducing the duration of acute neuropathy in colon

cancer

#### General information

##### Reason for update

##### Acronym

OIPN

##### IRCT registration information

IRCT registration number: **IRCT20150726023349N5**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

##### Registration date

2022-11-28, 1401/09/07

##### Registrant information

##### Name

Mohsen Esfandbod

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 982 181 631

##### Email address

sfandbod@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-01-08, 1401/10/18

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of melatonin efficacy in prophylaxis of Oxaliplatin induced acute peripheral neuropathy in FOLFOX regimen in patients with colon cancer

**Public title**

Evaluation of therapeutic effect of melatonin to improve nerve injury due to oxaliplatin

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

All colon cancer patients with indication of adjuvant chemotherapy

**Exclusion criteria:**

All patients with history of DM or any form of peripheral nerve injury

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we will use the Restricted Randomization (Block Randomization) method. Blocking is usually used in order to balance the number of samples assigned to each of the studied groups. This feature helps the researchers to have the same number of samples assigned to each of the studied groups in cases where intermediate analyzes are needed during the sampling process. The size of all the blocks is equal and we will have 10 blocks in this two-group experiment (including 5 participants in the intervention group and 5 participants in the control group). The randomization tool is to use a table of random numbers with even and odd numbers for the intervention and control groups, respectively. For concealment, we use allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the allocated group is not known before the individual is allocated. By using opaque letter envelopes sealed with a random sequence in (Sequentially numbered, sealed, opaque envelopes), each of the random sequences created in this method is recorded on a card and the cards are placed inside the letter envelopes in order They are placed. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same

order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This is a double blind randomised control trial in outpatient clinic and medical oncology ward of cancer institute Neither the therapist nor the patient knows whether they have been given a placebo or a drug

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Research Institute for Oncology, Hematology and Cell Therapy - Tehran

**Street address**

Research Institute for Oncology, Hematology and Cell Therapy Tehran University of Medical Sciences, Shariati Hospital, Karegar Ave., Jalal Al-Ahmad, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Approval date**

2022-03-16, 1400/12/25

**Ethics committee reference number**

IR.TUMS.HORCSCT.REC.1400.037

**Health conditions studied****1****Description of health condition studied**

Oxaliplatin- induced neuropathy, Chemotherapy- induced neuropathy

**ICD-10 code**

C18.8

**ICD-10 code description**

Malignant neoplasm of overlapping sites of colon

**Primary outcomes**

## 1

### Description

The reduction rate in percentage of the incidence of neuropathy in the involved patients receiving melatonin

### Timepoint

Symptoms of neuropathy asked from the patients in the form of some questionnaire before, in the first 48 hours of beginning of chemotherapy and 1week later, after every course of chemotherapy

### Method of measurement

collection of the information in the form of questionnaires: NCI- CTCAE<sub>9</sub>, OSNS, NPSI, EORTC QLQ-C<sub>2</sub>.

## Secondary outcomes

## 1

### Description

Prophylaxis for neuropathy in patients with colon cancer under treatment with oxaliplatin an irreversible complication of this treatment

### Timepoint

one and half a year

### Method of measurement

By neuromuscular evaluation (EMG and NCV) and physical examination and questionere

## Intervention groups

## 1

### Description

Intervention group: 1. receiving FOLFOX chemotherapy containing oxaliplatin receiving melatonin tablets ,One pill with a dose of 10 mg (manufactured by Jalinous pharmaceutical company) every night before sleeping for three months along with 1st to 6th course of their chemotherapy

### Category

Treatment - Drugs

## 2

### Description

Control group: 1. receiving FOLFOX chemotherapy containing oxaliplatin , receiving placebo ,One pill (manufactured by Jalinous pharmaceutical company) every night before sleeping for three months along with 1st to 6th course of their chemotherapy

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Cancer Institue Imam khomeini Hospital

#### Full name of responsible person

Homa Razavidehkordi

#### Street address

Imam Khomeini Hospital Complex, End of the Keshavarz Blvd., Qarib St., Tehran, Iran

#### City

Tehran

#### Province

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#### Postal code

1419733141

#### Phone

+98 21 6693 8083

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+98 21 6658 1593

#### Email

homa.razavi84@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Akbar Fotouhi

#### Street address

Keshavarz BLVD Ghods st. Tehran University of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Phone

+98 21 81631

#### Fax

+98 21 81631

#### Email

tumspr@tums.ac.ir

#### Web page address

<https://www.tums.ac.ir/>

#### Grant name

Dr Akbar Fotouhi

#### Grant code / Reference number

1400-3-222-56698

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

Yes

#### Title of funding source

Tehran 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Homa Razavidehkordi

**Position**

fellowship of hematology and oncology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohsen Esfandbod

**Position**

Associate professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Hematology

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sfandbod@sina.tums.ac.ir12345

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fariba Zarrabi

**Position**

Non-faculty

**Latest degree**

Master

**Other areas of specialty/work**

Medical Genetics

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**Email**

zarrabi.fa@gmail.com

**Web page address**

## 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**

The personal information of patients is not available for individuals but if needed we search them in the medical file and finally we release them as some questionair and analyse them

**When the data will become available and for how long**

Informationd are available from January 8, 2022 until September 23,2023

**To whom data/document is available**

Informations are available for the researchers of academic institutions

**Under which criteria data/document could be used**

Informations are available for the reaserchers in academic institutions and all physicians and reaserchers in hospitals and medical clinics

**From where data/document is obtainable**

1. homa.razavi84@yahoo.com
2. sfandbod@sina.tums.ac.ir12345

**What processes are involved for a request to access data/document**

With contacting to mentioned Email addresses, the informations are reachable in two weeks after receiving the Email

**Comments**