Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 ceses 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/m2 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

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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- CTCAE۴ OSNS, NPSI, EORTC QLQ-C۳۰

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
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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
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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

Academic

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

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Person responsible for scientific inquiries

Contact

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Mohsen Esfandbod

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Hematology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Fariba Zarrabi

Position
Non-faculty

Latest degree
Master

Other areas of specialty/work
Medical Genetics

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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