

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Efficacy of melatonin for the treatment of moderate to severe vincristine-induced neuropathy in pediatric malignancies

#### Protocol summary

##### Study aim

In this study, the effectiveness of melatonin in the treatment of moderate to severe neuropathies induced by vincristine in pediatric malignancies was investigated.

##### Design

Randomized, two-blinded, parallel, placebo-controlled clinical trial with 10 patients in each group.

##### Settings and conduct

This two blind study will be done in Tehran Pediatric Medical Center. Health care providers and patients are blind. Patients with vincristine-induced neuropathy fall into two groups using block randomization. One group received placebo and other received melatonin. In the treatment group, patients receive melatonin (weight less than 40 kg: 3 mg, weight more than 40 kg: 5 mg) daily for 30 days 4 hours before bedtime and after dinner. In the placebo group, the placebo tablet will be received for 30 days too. Patients will be evaluated every two weeks, ie the second and fourth weeks. In each assessment, children are evaluated for the extent of neuropathy, timing of complete recovery and quality of life.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: 6-12 years old, Patients with ALL, Incidence of neuropathy following receiving vincristine  
Exclusion Criteria: Hypersensitivity to melatonin, Patients over 12 years of age, CNS tumor (except meduloblastoma), focal neurological symptoms, CNS metastasis, Other neuromuscular disorders (traumatic brain injury, cerebral palsy), Recurrent diseases , Unstable hemodynamic status, Amputation of upper and lower limbs

##### Intervention groups

Intervention group: Melatonin tablet will be taken.  
Control group: Placebo tablet will be taken.

##### Main outcome variables

Neuropathy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200710048068N1**

Registration date: **2022-06-21, 1401/03/31**

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

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

##### Registration date

2022-06-21, 1401/03/31

##### Registrant information

##### Name

Zahra Yari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6691 6847

##### Email address

zyari870@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-09, 1401/01/20

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of melatonin for the treatment of moderate to severe vincristine-induced neuropathy in pediatric malignancies

#### Public title

Efficacy of melatonin for the treatment of moderate to severe vincristine-induced neuropathy in pediatric malignancies

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age: 6-12 years old Patients with ALL Incidence of neuropathy following receiving vincristine

##### Exclusion criteria:

Hypersensitivity to melatonin Patients over 12 years of age CNS tumor (except medulloblastoma), focal neurological symptoms, CN metastasis Other neuromuscular disorders (traumatic brain injury, cerebral palsy) Recurrent diseases Unstable hemodynamic status Amputation of upper and lower limbs

#### Age

From **6 years** old to **12 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method of this study is permuted block randomization individually. The randomized list of numbers 1 to 20 is randomly divided into two groups A or B, and the admitted patients are listed in group A or B, respectively.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

This study is a two blind clinical trial conducted at children's medical center. The producing company were asked to produce the melatonin pills and placebo pills with the same app so that they are indistinguishable from each other. The drugs were delivered to the researcher in 2 separate packages (packet number 1 and packet number 2), One packet was a placebo pill and the other was a melatonin pill. In a sealed letter the content of each group were revealed. Patients, researcher and statistic expert were blinded.

#### Placebo

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 Sciences

##### Street address

Tehran University of Medical Science

##### City

Tehran

##### Province

Tehran

##### Postal code

0

#### Approval date

2020-07-08, 1399/04/18

#### Ethics committee reference number

IR.TUMS.TIPS.REC.1399.040

## Health conditions studied

### 1

#### Description of health condition studied

chemotherapy induced neuropathy

#### ICD-10 code

G63.1\*

#### ICD-10 code description

Polyneuropathy in neoplastic disease

## Primary outcomes

### 1

#### Description

Neuropathy

#### Timepoint

The second and fourth weeks after starting treatment

#### Method of measurement

ped-mTNS and PCIN questionnaires

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

The second and fourth weeks after starting treatment

#### Method of measurement

Peds QL Questionnaire

## Intervention groups

## 1

### Description

Intervention group: Patients receive melatonin (weight less than 40 kg: 3 mg, weight more than 40 kg: 5 mg) for 30 days 4 hours before bedtime and after dinner.

### Category

Prevention

## 2

### Description

Control group: Patients receive placebo for 30 days 4 hours before bedtime and after dinner.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Children's Medical Center

#### Full name of responsible person

Toktam Faghihi

#### Street address

Keshavarz Boulevard

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733151

#### Phone

+98 21 6695 4709

#### Email

tfaghihi@razi.tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Akbar Fotouhi

#### Street address

16 Azar Ave, Keshavarz Blvd

#### City

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#### Postal code

1419733141

#### Phone

+98 21 6658 1692

#### Email

zyari870@gmail.com

#### Grant name

#### Grant code / Reference number

### 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

Toktam Faghihi

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Pharmacotherapy

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Toktam Faghihi

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Pharmacotherapy

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Zahra Yari  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Pharmacotherapy  
**Street address**  
No. 2, Homa Alley, South Jamalzadeh Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1313815435  
**Phone**  
+98 21 6691 6847  
**Email**  
zyari870@gmail.com

## 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 data like check list and demographic data will be published in form of article.

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

At the end of study and after publication

### To whom data/document is available

Scientific researchers

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

For more researches

### From where data/document is obtainable

Toktam Faghihi

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

After acceptance by Toktam Faghihi

### Comments