

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The evaluation of the effect of oral melatonin in the treatment of oral mucositis and oral pain reduction in patients with upper gastrointestinal tract tumors

Protocol summary

Study aim

The evaluation of the effect of oral melatonin on the treatment of oral mucositis and oral pain reduction in patients with upper gastrointestinal tract tumors

Design

Randomized, double-blinded, placebo-controlled, phase 2 trial on 98 patients. The permuted block randomization model with block size 4 will be conducted.

Settings and conduct

This study is a randomized double-blinded placebo-controlled clinical trial (the researcher, patient, and physician are blind). In this study, 98 patients with gastric or esophageal cancer referred to Shahid Rajaei Hospital will be recruited. Included patients are those who have developed grade 1 or 2 oral mucositis (according to WHO classification) after receiving a fluorouracil (5-FU) chemotherapy regimen.

Participants/Inclusion and exclusion criteria

Age of 18 years or above, Not anticoagulated or have coagulation disorders, No history of seizure, No history of dementia, No history of depression, No history of diabetes, Signing the informed consent form, Patients with gastric or esophageal cancer that is under treatment with a f-FU-containing regimen and have developed grade 1 or 2 oral mucositis according to the WHO classification

Intervention groups

In this study, the effect of 20 mg/day oral melatonin in the treatment of oral mucositis will be evaluate. The intervention group will receive the standard treatment for oral mucositis plus 20 mg/day melatonin tablet. The control group will receive the standard treatment for oral mucositis plus placebo tablet.

Main outcome variables

Determination of the effect of oral melatonin on reducing the severity of mucositis and oral pain caused by chemotherapy for upper gastrointestinal tumors;

Determination of side effects of melatonin compared with placebo; Determination of the effect of melatonin on patients' quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220426054666N1**

Registration date: **2022-06-01, 1401/03/11**

Registration timing: **prospective**

Last update: **2022-06-01, 1401/03/11**

Update count: **0**

Registration date

2022-06-01, 1401/03/11

Registrant information

Name

Behin Marzban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3256 7175

Email address

behin1376@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-21, 1401/05/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of oral melatonin in the treatment of oral mucositis and oral pain reduction in patients with upper gastrointestinal tract tumors

Public title

The evaluation of the effect of oral melatonin in the treatment of oral mucositis and oral pain reduction in patients with upper gastrointestinal tract tumors

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Not anticoagulated No history of seizure No history of dementia No history of depression No history of diabetes Signing the informed consent form Patients with gastric or esophageal cancer that is under treatment with a f-FU-containing regimen and have developed grade 1 or 2 oral mucositis according to the WHO classification

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are placed in 4-person blocks using permuted block randomization method. In block randomization, blocks with the same or different sizes of individuals are first identified. Then, within each block, the assignment of individuals to each of the treatment groups is randomly determined. The number of blocks and people inside each block is determined according to the sample size of the whole study. Randomization software will be used to obtain individual sequences for blocks and random assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher, patient and physician are blind to this study. In this study, the patient will be kept unaware of the group therapy with the help of a placebo. Also, the person who evaluates and treats the patients will be kept informed of the type of treatment. In this study, only one person (supervisor) will be aware of the allocation of

people to treatment groups and randomization codes, and other people implementing the project or colleagues, as well as patients of the type of treatment and groups are kept unaware and drugs and interventions to the coded form will be provided and will be decoded only at the end of the code study (eg drug / group A and B). Therefore, the drugs as well as the placebo will be provided in the same form and without a name and only with a code for the treating physician and patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Alborz University of Medical Sciences

Street address

Office of the Ethics Committee-2th floor-Deputy of Research and Technology-Safarian street-Golshahr Ave

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.ABZUMS.REC.1401.014

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

oral mucositis and oral pain in patients with upper gastrointestinal tract tumors

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mucositis severity according to WHO classification and severity of patient oral pain according to common terminology criteria for adverse events (CTCAE) version 5.0 and Visual Analog Scale

Timepoint

Daily

Method of measurement

WHO scale for oral mucositis ,common terminology criteria for adverse events (CTCAE) version 5.0 ,Visual Analog Scale

Secondary outcomes

1

Description

quality of life

Timepoint

daily

Method of measurement

European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC)

Intervention groups

1

Description

Intervention group: Standard mucositis treatment plus melatonin tablets 20 mg/daily. Treatment will be continued until complete relief of symptoms (up to 2 weeks).

Category

Treatment - Drugs

2

Description

Control group: Standard mucositis treatment plus placebo tablets. Treatment will be continued until complete relief of symptoms (up to 2 weeks).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Behin Marzban

Street address

Shahid Rajaei street-Hesarak

City

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3197635141

Phone

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Rajaei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Hatam Godini

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Deputy of Research and Technology-Saffarian Alley-Golshahr Ave

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Behin Marzban

Position

Doctor of pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person
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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

After deleting personal information ,the Spss file would be shared.

When the data will become available and for how long

From 1402 onward

To whom data/document is available

After authentication of researchers, they are permitted to access to data.

Under which criteria data/document could be used

The only acceptable analyze are of researchers.

From where data/document is obtainable

To take data/document refer to the responsible author of the article.

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

Provided applicants being authenticated, they could access to data after utmost one month.

Comments