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 intevention 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

Karaj

Province

Alborz

Postal code

3197635141

Phone

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Email

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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Faculty of Pharmacy building-next to Bahonar Hospital-Valiasr St.-Shura Boulevard

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Mehdi Mohammadi
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Behin Marzban
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Doctor of pharmacy
Latest degree
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Phone
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Email
pharmacy@abzums.ac.ir

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