Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the effect of Melatonin mouthwash on prevention of chemotherapy-induced oral mucositis, a randomized double blinded placebo controlled clinical trial

Protocol summary

Study aim
Investigation of the effect of Melatonin mouthwash on prevention of chemotherapy-induced oral mucositis, a randomized double blinded placebo controlled clinical trial.

Design
Phase III randomized, double-blind, placebo-controlled clinical trial will be conducted on 70 patients, using block randomization method to randomize the experiment.

Settings and conduct
Study site: Shahid Rajaei Educational and Medical center
The mouthwash bottles will be numbered according to the randomized list and by a person who was not involved in patient registry and examination of oral mucositis; all involved in patient registry and examination of oral mucositis will not be informed about the numbers related to drug or placebo during the study.

Participants/Inclusion and exclusion criteria
Entry requirements: Age 18 and above. A patient with malignant solid tumor and candidate for chemotherapy (receiving medications with potential of almost similar mucositis: Cyclophosphamide, Doxorubicin, Fluorouracil, Methotrexate, Gemcitabine, Dacarbazine, and Cisplatin). Karnofsky status greater than or equal to 60%. Oral and written satisfaction (consent) of patients to participate in survey. No entry requirements: Inability in using the mouthwash. Smoking. Increasing hypersensitivity to melatonin or any other components used in formulation. History of head and neck radiotherapy. Having any lesions inside the mouth.

Intervention groups
Patients within intervention group will receive 4 ml of 0.3% melatonin mouthwash three times a day, and the patients of the control group will use 4 ml of placebo mouthwash (without active ingredient of melatonin in the formulation) made in Alborz School of Pharmacy three times a day. The mouthwash will be used from the first day of chemotherapy, for 6 weeks.

Main outcome variables
Intensity of mucositis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220213054015N1**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **prospective**

Last update: **2022-04-12, 1401/01/23**
Update count: **0**

Registration date
2022-04-12, 1401/01/23

Registrant information

Name
Aida Abdi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-20, 1401/02/30

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effect of Melatonin mouthwash on prevention of chemotherapy-induced oral mucositis, a randomized double blinded placebo controlled clinical trial

Public title
Investigation of the effect of Melatonin mouthwash on prevention of chemotherapy-induced oral mucositis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 and above. A patient with malignant solid tumor and candidate for chemotherapy (receiving medications with potential of almost similar mucositis: Cyclophosphamide, Doxorubicin, Fluorouracil, Methotrexate, Gemcitabine, Dacarbazine, and Cisplatin). Karnofsky status ≥ ۶۰%. Oral and written satisfaction (consent) of patients to participate in survey.
Exclusion criteria:
Inability in using the mouthwash. Smoking. Increasing hypersensitivity to melatonin or any other components used in formulation. History of head and neck radiotherapy. Having any lesions inside the mouth.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly classified in two classes of melatonin and placebo using block randomization method (block of size 6), to randomize the experiment. The randomization sequence using a computer-based randomized list will be determined by a person not involved in patient registry, then the mouthwash bottles will be numbered according to the randomized list and by a person who was not involved in patient registry and examination of oral mucositis; anyone involved in patient registry and examination of oral mucositis will not be informed about the numbers related to drug or placebo during the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blinded clinical trial, which means the patient and the researcher who provide the drug or placebo to the patients and evaluate the patients, are not aware whether the mouthwash is a drug or placebo.for this purpose, after making melatonin mouthwash and placebo which will both be exactly the same in appearance, these mouthwashes are poured into totally the same bottles by a researcher who is not involved in patient recruitment and examination of oral mucositis; then they are numbered in blocks of 6 size on a list of random computer numbers. it is worth noting that this list and that each number belongs to drug or placebo, is only available to the senior researcher (supervisor) who is not involved in the patient recruitment and examination of oral mucositis.Then, these completely similar bottles, on which only one number is installed, are given to the student (person responsible for patient recruitment) so that the student can provide the bottles to the patients in the order of the number of patients who entering the study.
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
Safareyan St., Golshahr Ave.
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Approval date
2022-02-01, 1400/11/12
Ethics committee reference number
IR.ABZUMS.REC.1400.311

Health conditions studied

1

Description of health condition studied
chemotherapy-induced oral mucositis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of mucositis
Timepoint
At the beginning of the study (before initiating intervention), as well as, 7, 14, 21, 28, 35, and 42 days after using the melatonin mouthwash
Method of measurement
World Health Organization Toxicity Scale

Secondary outcomes

1

Description
Intensity of pain
Timepoint
At the beginning of the study (before initiating intervention), as well as, 7, 14, 21, 28, 35, and 42 days after using the melatonin mouthwash.
Method of measurement
Visual analog scale

2

Description
Quality of Life
Timepoint
At the beginning of the study (before initiating intervention), as well as, 7, 14, 21, 28, 35, and 42 days after using the melatonin mouthwash
Method of measurement
EORTC Quality of Life Questionnaire QLQ-C30

Intervention groups

1

Description
Intervention group:Patients will gargle 4 ml of melatonin mouthwash made in Alborz School of Pharmacy, three times a day (a measuring cup with defined volume will be provided to facilitate the use). The patients will be asked to keep the mouth wash in their mouth for a minute or as long as possible, before spitting out. The patients will be asked to avoid eating for the next 30 min after using the mouthwash. The mouthwash will be will be utilized from the first day of chemotherapy and will continue for the next 6 weeks. The purpose and advantages of this survey will be thoroughly explained to the patients to ensure the consistent use of mouthwash through the survey; patients will also be inquired to join the survey in case of possible consistent accompaniment and complete consent. The practice of mouthwash by the patients will regularly be monitored via telephone calls or social media. It should be noted that some errors might inevitably emerge during the survey.
Category
Prevention

2

Description
Control group:Patients will gargle 4 ml of placebo mouthwash made in Alborz School of Pharmacy (without melatonin active ingredient in mouthwash formulation) three times a day (a measuring cup with defined volume will be provided to facilitate the use). The patients will be asked to keep the mouth wash in their mouth for a minute or as long as possible, before spitting out. The patients will be asked to avoid eating for the next 30 min after using the mouthwash. The mouthwash will be will be utilized from the first day of chemotherapy and will continue for the next 6 weeks. The purpose and advantages of this survey will be thoroughly explained to the patients to ensure the consistent use of mouthwash through the survey; patients will also be inquired to join the survey in case of possible consistent accompaniment and complete consent. The practice of mouthwash by the patients will regularly be monitored via telephone calls or social media. It should be noted that some errors might inevitably emerge during the survey.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Educational and Medical Center
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Deputy of research and technology
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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
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Full name of responsible person
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Position
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Person responsible for updating data

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Latest degree
A Level or less
Other areas of specialty/work
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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
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected data.

When the data will become available and for how long

After the end of the study and its publication.

To whom data/document is available

Researchers.

Under which criteria data/document could be used

Use for review studies.

From where data/document is obtainable

Corresponding author email.

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

Sending email.

Comments