Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Examining the effect of cinnamol and mint mouthwash on oral mucositis in chemotherapy patients: a clinical trial investigation.

Protocol summary

Study aim

Investigating the impact of cinnamol and mint mouthwash on oral mucositis in patients undergoing chemotherapy

Design

A clinical trial was conducted on 126 patients, utilizing a controlled group design with parallel groups, double-blinded, and randomized by using a block randomization method in groups of six.

Settings and conduct

This research comprises a randomized clinical trial to be carried out in three distinct groups at Khoansazi Hospital in Arak. Prior to the initiation of chemotherapy, all study participants will receive standardized instruction on proper oral hygiene practices, such as brushing and flossing, in accordance with the guidelines outlined by the World Health Organization. Assessment of oral mucositis will be conducted using the WHO checklist on the first, seventh, and fourteenth days following the commencement of the intervention. Both the researcher and the participants involved in the study will be blinded to the group assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Written consent from participants؛ Full consciousness ؛ Minimum age 18 and maximum 70 years؛ Having oral mucositis (minimum score of 1) Exclusion criteria: Lack of consent to continue participating in the research؛Allergy to or oral or solution؛The patient's death؛The history of using mint and cinnamol mouthwashes؛Suffering from gum and tooth diseases

Intervention groups

In the routine mouthwash group, participants gargle three times a day with either a placebo that resembles mint drops or cyanmol as part of their daily treatment regimen. In the mint group, mint essence mouthwash is used. They believe that the standard treatment provided by the attending physician will continue as usual, with the exception of using topical mouthwash. In the Cinnamol group, participants use Cinnamol mouthwash.

Main outcome variables

Measuring the possible improvement of mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240304061169N1**
Registration date: **2024-07-22, 1403/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-22, 1403/05/01**
Update count: **0**

Registration date

2024-07-22, 1403/05/01

Registrant information

Name

Negin Gholami

Name of organization / entity

Khomein University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Examining the effect of cinnamol and mint mouthwash on oral mucositis in chemotherapy patients: a clinical trial investigation.

Public title
Examining the effect of cinnamol and mint mouthwash on oral mucositis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Written consent from participants Written consent from participantsFull consciousness Admitted to the oncology department of Khansari Hospital Similar treatment protocol age is age 18 maximum age is maximum years. years Having oral mucositis (minimum score of 1)
Exclusion criteria:
Lack of consent to continue participating in the research Allergy to or oral or solution The patient's death The history of using mint and cinnamol mouthwashes Continuous use of painkillers and drugs Suffering from gum and tooth diseases
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants will be randomized into three groups for treatment: a control group receiving routine mouthwash, a first intervention group receiving mint mouthwash, and a second intervention group receiving cinnamol mouthwash. The randomization will be conducted using a 6-block method. Six cards are selected. The letter A is written on two cards, the letter B is written on the other two cards, and the letter C is written on the remaining two cards. To conceal the cards, they are placed inside the envelope and turned over several times to obscure their order. When each participant enters, a card is selected for them, and the selected card is discarded. This process is repeated for the next five patients until six people are identified. Then, in the same manner, randomization will be conducted for other groups of 6 people to achieve the desired sample size. Write down the person associated with each block so that the final analysis of the information can be conducted.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, which is double-blind, the research samples and the researcher conducting the intervention in this study will be blinded. It has been tried to observe the similarity of the intervention in the groups as much as possible
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Khomein University of Medical Sciences
Street address
Azadi street, Khomein
City
Khomein
Province
Markazi
Postal code
3881743364
Approval date
2024-06-19, 1403/03/30
Ethics committee reference number
IR.KHOMEIN.REC.1403.011

Health conditions studied

1

Description of health condition studied
Oral mucositis
ICD-10 code
K13
ICD-10 code description
Other diseases of lip and oral mucosa

Primary outcomes

1

Description
Oral mucositis
Timepoint
on the first, seventh and fourteenth days
Method of measurement
Scoring of patients' oral mucositis using the WHO scoring system

Secondary outcomes

empty

Intervention groups

1

Description

In the mint group (provided by Barij Essan pharmaceutical company), participants are instructed to utilize mint essence mouthwash, which can be obtained from pharmacies, for a duration of 14 days. The mouthwash should be used three times a day following teeth brushing sessions scheduled in the morning, noon, and night. The recommended method involves diluting 10 drops of peppermint essential oil in 30 cc of water, gargling the solution for one minute, and refraining from consuming any food for an hour thereafter. It is important to note that participants should continue with their regular treatment regimen as prescribed by their healthcare provider, with the exception of using any other topical mouthwash. Group B participants are advised to follow the same protocol, receiving daily mouthwash until the completion of the 14-day period.

Category

Treatment - Drugs

2

Description

Intervention group: In the Cinnamol mouthwash group(provided by Gol Daro pharmaceutical company), participants are instructed to use the mouthwash three times daily following tooth brushing (in the morning, at noon, and at night) for a duration of 14 days. Specifically, individuals are advised to dilute 20-25 drops of the Cinnamol solution in 30 cc of water, gargle with the mixture for one minute, and refrain from eating for one hour thereafter. During this period, participants are to continue with their regular treatment regimen as prescribed by their attending physician, with the exception of using any other topical mouthwash.

Category

Treatment - Devices

3

Description

In the control group, in addition to the routine treatment, a placebo is also gargled three times a day, in the morning, for 1 minute (receive mouthwash daily until the 14th day) (provided by Barij Essan pharmaceutical company),. After using mouthwash, patients do not consume food or liquids for 1 hour (group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Khansari Hospital
Full name of responsible person
Mehran Akbari
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khomein University of Medical Sciences
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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
Khomein 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
Khomein University of Medical Sciences

Full name of responsible person
Mehran Akbari

Position
Faculty instructor

Latest degree
Master

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available