Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the Effect of Using Mouthwash Solution Containing Hydroalcoholic Extract of Pomegranate and Turmeric on Oral Mucositis Due to Chemotherapy in Cancer Patients, a Triple blind, Randomized, Controlled Trial

Protocol summary

Study aim
The effect of pomegranate and turmeric mouthwash on chemotherapy-induced mucositis

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 2 on 60 patients.A table of random numbers is used for randomization.

Settings and conduct
The study will be performed on 60 patients undergoing chemotherapy at Shahid Rahimi Hospital in Khorramabad. The control group continued with placebo mouthwash and the intervention group continued with pomegranate and turmeric mouthwash. Both groups also accepted routine treatment. It was then tested by a specific person on days 0, 7 and 14 of the intervention. In order to blind the researcher and other people involved in the study, the random grouping of participants will be assigned to one of the nurses, and in order to blind the patients, the mouthwash will contain the same extract and placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients 18 to 65 years Patients are able to complete the questionnaire Absence of serious dental problems and damage to the oral mucosa Do not use dentures Do not use anti-inflammatory and other mouthwash solutions during research No other systemic diseases No history of smoking, drugs and alcohol No oral candidiasis or herpes simplex Do not use cryotherapy for six weeks before the study Exclusion criteria: Patient dissatisfaction History of allergies to turmeric and pomegranate, lidocaine, antacids, diphenhydramine and dexamethasone Inability of the patient to implement the treatment protocol Patient death due to failure to respond to anticancer therapy Combination therapies such as radiation therapy

Intervention groups
Intervention group: routine mouthwash plus mouthwash containing pomegranate and turmeric extract Control group: routine mouthwash plus placebo mouthwash

Main outcome variables
Degree of mucositis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200721048159N1**
Registration date: **2021-04-10, 1400/01/21**
Registration timing: **prospective**

Last update: **2021-04-10, 1400/01/21**
Update count: **0**

Registration date
2021-04-10, 1400/01/21

Registrant information

Name
Forouzan Ahmadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 3312 0239

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ahmadpoor.f@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-17, 1400/02/27

Expected recruitment end date
2021-11-18, 1400/08/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Using Mouthwash Solution Containing Hydroalcoholic Extract of Pomegranate and Turmeric on Oral Mucositis Due to Chemotherapy in Cancer Patients, a Triple blind, Randomized, Controlled Trial

Public title
Evaluation of the Effect of Pomegranate and Turmeric Mouthwash on Oral Mucositis Due to Chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients in the age range of 18 to 65 years Cancer patients with chemotherapy-induced oral inflammation Patients are able to complete a questionnaire and collaborate with the researcher Absence of serious dental problems or teeth damaging the oral mucosa or sharp fillings Do not use dentures Do not use anti-inflammatory and other mouthwash solutions during research No other systemic diseases No history of smoking, drugs and alcohol No oral candidiasis (fungus) or herpes simplex (virus) Do not use cryotherapy for six weeks before the study
Exclusion criteria:
Dissatisfaction with participating in the study Participate in another clinical trial at the same time History of allergies to turmeric and pomegranate, lidocaine, antacids, diphenhydramine and dexamethasone Inability of the patient to implement the treatment protocol Patient death due to failure to respond to anticancer therapy Combination therapies such as radiation therapy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are used by stratified random blocking method (classes are intended to match the two groups in terms of disease grades so that patients with grade 1 and 2 in one class and patients with grade 3 and 4 in the other class) to two) An equal group of control and intervention will be assigned. The method of allocating samples to the two groups will be that considering the mucosal grade as a class, the method of 4 random blocks will be used to assign patients to two groups A (intervention) and group B (control). To do this, first write a list of blocks and assign numbers to them. (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then using From the table of random numbers and randomly selected numbers between 1 and 6 and finally the list of treatment allocation will be formed based on a sequence of letters A and B.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a Triple-Blind Study and the blinding method is such that the researcher and the participating patients and data analyst will be unaware of which participant is in which group. In order to blind the researcher, random grouping of participants and prescribing mouthwash to them will be assigned to one of the ward doctors or nurses who has no role in the trial. In order to blind the participating patients, mouthwash containing extract and placebo mouthwash will taste as much as possible. And will have a similar appearance and will be prescribed in identical bottles. None of the members of the Data Safety and Supervision Committee, as well as the person evaluating the outcome and analyzing the data, will have a role in the randomization and use of mouthwash by participating patients and will not be informed which mouthwash each patient will use.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences
Street address
Naser Khosrow Square, Roudaki St., Chaghervand Alley, No. 10
City
khorram abad
Province
Lorestan
Postal code
1234567898657678
Approval date
2021-03-09, 1399/12/19

Ethics committee reference number
IR.LUMS.REC.1399.363

Health conditions studied

1

Description of health condition studied
Oral mucositis due to antineoplastic therapy
ICD-10 code
K12.31
ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
Grade of mucositis based on WHO scale
Timepoint
Evaluation of grade of mucositis at the beginning of the study, 7 and 14 days after mouthwash containing pomegranate and turmeric extract
Method of measurement
Standard questionnaire and patient examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group Herbal mouthwash containing 6.25% hydroalcoholic extract of pomegranate peel and 0.1% hydroalcoholic extract of turmeric, once every 6 hours, 30 drops in water to reach a volume of 10 ml and hold in the mouth for 2 minutes and then gargle They will swallow. The patients will receive herbal mouthwash for a week in addition to routine treatment.
Category
Treatment - Drugs

2

Description
Control group: The control group poured 30 drops of placebo into the mouth every 6 hours until it reached a volume of 10 ml and was kept in the mouth for 2 minutes, then gargled and swallowed.The patients will receive placebo mouthwash for a week in addition to routine treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahimi Hospital
Full name of responsible person
Forouzan Ahmadpour
Street address
Shahid Seyed Fakhreddin Rahimi Hospital, not far from Safavid Bridge, Mojahedin Street, Azadi Square
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Khorramabad
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6813816314
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Forouzan Ahmadpour
Street address
Shahid Seyed Fakhreddin Rahimi Hospital, not far from Safavid Bridge, Mojahedin Street, Azadi Square
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Lorestan
Postal code
6813816314
Phone
+98 66 1223 6141
Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Khorramabad University of Medical Sciences
Proportion provided by this source
30
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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Forouzan Ahmadpour

Position
Assistant professor of clinical pharmacy

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available