Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of silymarin and honisol mouthwashes with standard care in preventing radiotherapy-induced oral mucositis: a randomizedclinical Trial

Protocol summary

Study aim

Comparison of the incidence of oral mucositis among the three study groups. Comparison of the severity of oral mucositis among the three study groups.

Design

The study is designed as a Phase II, randomized, double-blind, controlled trial with a parallel-group design involving 63 participants (21 participants per group). Randomization and Allocation:To ensure equal distribution among the three arms, balanced block randomization with a block size of three will be employed. The randomization sequence will be produced via Random Allocation Software.

Settings and conduct

TheConducted at Sadaf Clinic (Imam Khomeini Hospital Complex), this study employs a blinded design. Randomization and allocation will be managed by a non-clinical third party to prevent bias. Clinicians and assessors will be blinded to treatments, which are visually identical. Participants will rinse thrice daily for one minute (expectorating thereafter). Assessments start one week post-radiotherapy, with follow-ups lasting one to two months. All adverse effects will be monitored across all groups

Participants/Inclusion and exclusion criteria

:Patients undergoing head and neck radiotherapy due to cancer. The radiotherapy regimen consists of 30 sessions with a total dose of 75 Gy. Exclusion Criteria:Patients with systemic diseases causing oral ulceration or mucositis. Pregnant women. Patients undergoing concurrent chemoradiotherapy.

Intervention groups

The particieThe three study arms consist of: (1) Control: standard care (normal saline, Nystatin, and dietary advice); (2) Silymarin: a prepared mouthwash using Gol Daru tablets dissolved in water; and (3) Hanisol: Hanisol syrup (Manitasa) used as a mouthwash. All interventions require a one-minute rinse three times daily, followed by expectoration

Main outcome variables

The incidence and severity of oral mucositis will be compared among the three study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260802070494N1**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date

2026-09-17, 1405/06/26

Registrant information

Name

Hossein Ghezelsefloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of silymarin and honisol mouthwashes with standard care in preventing radiotherapy-induced oral mucositis: a randomizedclinical Trial

Public title
Effect of honeysol and silymarin in oral mucositis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing radiotherapy for head and neck cancer The radiotherapy regimen for patients consists of 30 sessions with a total dose of 75 Gray
Exclusion criteria:
Patients with systemic diseases that cause oral ulceration and mucositis pregnant women; patients undergoing chemoradiotherapy.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **63**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated into the three study groups using a block-balanced randomization method with random blocks of three. The randomization sequence will be generated using block randomization software.
Blinding (investigator's opinion)
Double blinded
Blinding description
The randomization sequence and allocation envelopes were prepared and maintained by a person outside the clinical evaluation team to reduce the risk of allocation bias. The study drugs were identical in appearance. The treatment team and the evaluators of mucositis severity were blinded to the randomization sequence.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran university dormitories , North Kargar ,North Amirabad Town ,
City
Tehran
Province
Tehran
Postal code
1439957181
Approval date
2026-08-08, 1405/05/17
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1405.024

Health conditions studied

1

Description of health condition studied
Oral mucositis in patients with head and neck radiotherapy
ICD-10 code
K12.30
ICD-10 code description
Oral mucositis (ulcerative), unspecified

Primary outcomes

1

Description
Sevieeity of oral mucusitis
Timepoint
Before starting the study, 3 weeks later, 5 weeks later(end of the study)
Method of measurement
Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients used 5 cc of 0.9% normal saline as a mouthwash three times a day for 5 weeks, and then spit it out.The solution is stored in dark containers
Category
Placebo

2

Description

Intervention group: To prepare the silymarin mouthwash, 140 mg silymarin tablets (produced by Goldaru Pharmaceutical Company) will be used. Each tablet will be dissolved in 100 ml of sterile normal saline to obtain a uniform solution. To ensure complete dissolution, the tablet will first be crushed and then dissolved under gentle agitation. The prepared solution must be fresh and will be prepared on a daily basis. The final concentration of silymarin will be 140 mg/100 ml (1.4 mg/ml). After preparation, the solution will be stored in a dark, sealed container. Patients will be instructed to hold 10 ml of the solution in their mouth, gargle for 1 minute, and then expectorate it, three times a day. The recommended duration of 1 minute for using the silymarin mouthwash is based on standard protocols in pharmacological studies. This duration allows sufficient time for effective contact between the active ingredient and the oral mucosa to achieve maximum therapeutic effect. Previous studies on therapeutic mouthwashes have also frequently recommended 30-to-60-second intervals for optimal efficacy.

Category

Treatment - Drugs

3

Description

Intervention group: The Honey-Sol syrup, containing 20% honey and 5% turnip extract in a 120 ml volume, will be used as a mouthwash. The syrup will be mixed with sterile distilled water at a 1:2 (v/v) ratio. The solution will be stored in light-resistant (dark) containers. Patients will rinse their mouths with 10 ml of the solution three times daily and then expectorate it.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini (RA) Hospital, Sadaf Clinic

Full name of responsible person
Dr.soheila mahanifar

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Imam Khomeini (RA) Hospital, end of Keshavarz Blvd, North Kargar St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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+98 21 4279 4000

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dentistry@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Hossein Ghezelsefloi

Position
Dental student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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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
All information is suitable dor publication

When the data will become available and for how long
Access begina at the start of the year 1407 and remains available for six month

To whom data/document is available
It is exclusively for those employed at academic institution

Under which criteria data/document could be used
There is no limitation

From where data/document is obtainable
09354186303 is the researcer contact .hosseinghezel82@gmail.com is the researcher email address

What processes are involved for a request to access data/document
Inquiries directed to the researher will be answered whith in 24 hours including responses to emails

Comments