Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of mouthwash and in situ gel containing benzydamine hydrochloride in the management of radiotherapy-induced oral mucositis

Protocol summary

Study aim

Comparing the effects of mouthwash and mucoadhesive gel containing benzydamine hydrochloride in the management of oral mucositis caused by radiotherapy in cancer patients undergoing treatment

Design

Randomized, controlled clinical trial with parallel groups on 92 patients. randomization with PASS 2021

Settings and conduct

Shahid Ramezanzadeh Radiotherapy Center, Yazd One group was given benzydamine mouthwash and the other group was given mucoadhesive gel containing benzydamine.

Participants/Inclusion and exclusion criteria

Eligible patients include: patients over 18 years of age with head and neck cancer who require radiotherapy with a dose of at least 60 Gy and are willing to participate in the study, with the ability to rinse and gargle and not to smoke during radiotherapy. Patients with any source of infection in the mouth, Patients using dentures, History of allergy to chitosan or benzydamine, and Patients with a history of previous cancer treatment.

Intervention groups

In the intervention group, patients will be randomly assigned to receive a mucoadhesive gel containing the drug, prepared by the dental materials team according to standard procedures.In the control group, patients will be randomly assigned to receive benzydamine mouthwash (0.15%) available on the market from Elixir Pharmaceutical Company (Benzylazine).

Main outcome variables

1. Time of onset of oral mucositis (by recording the day of onset of mucositis symptoms from the start of radiotherapy), 2. Duration of mucositis (by recording the time in days from the onset of mucositis to complete recovery), 3. Severity of mucositis (based on the WHO scale after weekly intraoral examinations), and 4. Report of any observed side effects from the formulations. 5. Pain level due to mucositis based on the visual analogue scale (VAS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240928063187N3**
Registration date: **2025-11-22, 1404/09/01**
Registration timing: **prospective**

Last update: **2025-11-22, 1404/09/01**
Update count: **0**

Registration date

2025-11-22, 1404/09/01

Registrant information

Name

fatemeh owlia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3621 2222

Email address

f.owlia@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-01, 1404/09/10

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of mouthwash and in situ gel containing benzydamine hydrochloride in the management of radiotherapy-induced oral mucositis

Public title
Comparison of the effects of mouthwash and in situ gel containing benzydamine hydrochloride in the management of oral mucositis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age with head and neck cancer who require radiation therapy with a dose of at least 60 Gy. Willingness to participate in the study Have the ability to rinse and gargle They have no smoking during radiotherapy.
Exclusion criteria:
1) Patients with any source of infection in the mouth 2) Patients using dentures 3) History of allergy to chitosan or benzydamine 4) Patients with a history of previous cancer treatment.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be distributed into two groups using an online randomization program. In this study, block randomization is used to allocate eligible individuals in a 1:1 ratio to treatment groups (A, B). The block size is 4, and a total of 23 blocks are considered. Each block contains an equal number of interventions. PASS 2021 software is used to generate random sequences in blocks. The sealed envelope method is used to conceal the randomization sequence. An independent biostatistician in this study will generate the randomization sequence, and then the generated random codes will be placed in the envelope and sealed, and the researchers of this study will be unaware of the treatment type. Eligible individuals will be referred in order and included in the study according to the randomization sequence and sealed envelopes. The treatment will be prepared as treatment A or B by the pharmacist according to the randomization sequence.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yaz
Street address
Deha Fajr Boulevard, Imam Reza Street, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd1
City
Yazd
Province
Yazd
Postal code
3867765178
Approval date
2025-10-28, 1404/08/06
Ethics committee reference number
IR.SSU.DENTISTRY.REC.1404.045

Health conditions studied

1

Description of health condition studied
mucusitis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining and comparing the pain level of oral mucositis caused by radiotherapy in cancer patients before and after intervention in the mouthwash and mucoadhesive gel groups containing benzydamine
Timepoint
Follow-up will be conducted for 2 weeks and in 4 sessions (days 3, 5, 7 and 14).
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
تعیین و مقایسه شدت موکوز دهانی گروه ناشی از رادیوتراپی در بیماران سرطانی قبل و بعد از مداخله در دهانشویه و ژل مخاط چسب حاوی بنزیدآمین

Timepoint
Follow-up will be conducted for 2 weeks and in 4 sessions (days 3, 5, 7 and 14).

Method of measurement
WHO Mucositis Scale

Intervention groups

1

Description
Intervention group: Mucoadhesive gel in the form of a spray, which is sprayed on the mucosa every 8 hours (3 times a day), was developed by the dental materials team of Shahid Beheshti Dental Clinic. For two weeks

Category
Prevention

2

Description
Control group: Benzydamine mouthwash (0.15%) available on the market from Elixir Pharmaceutical Company (Benzylazine), measuring cups (5 to 15 ml), for two weeks, every 8 hours (3 times a day)

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ramezanzadeh Radiotherapy Center, Yazd

Full name of responsible person
Kimia Mashayekh

Street address
Deha Fajr Boulevard, Imam Reza Street, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd

City
Yazd

Province
Yazd

Postal code
3867765178

Phone
+98 35 3620 4760

Email
f.owlia@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Mohammad Arab Farashahi

Street address
Deha Fajr Boulevard, Imam Reza Street, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd

City
Yazd

Province
Yazd

Postal code
3867765178

Phone
+98 35 3620 4760

Email
f.owlia@ssu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Owlia

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Deha Fajr Boulevard, Imam Reza Street, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd

City
Yazd

Province
Yazd

Postal code
3867765178

Phone
+98 35 3620 4760
Email
f.owlia@ssu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Owlia
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Deha Fajr Boulevard, Imam Reza Street, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd
City
Yazd
Province
Yazd
Postal code
3867765178
Phone
+98 35 3620 4760
Email
f.owlia@ssu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
fatemeh owlai
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Deha Fajr Boulevard, Imam Reza Street, Faculty of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd
City
yazd
Province
Yazd
Postal code
3867765178
Phone
+98 35 3620 4760
Email
f.owlia@ssu.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
Comparison of the effects of mouthwash and mucoadhesive gel containing benzydamine hydrochloride in the management of radiotherapy-induced oral mucositis
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
Everyone has access.
Under which criteria data/document could be used
There are no special conditions.
From where data/document is obtainable
Via email address
What processes are involved for a request to access data/document
Request via email address only.
Comments