# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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**