Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Sumac spray and Benzydamine Hydrochloride spray on prevention of radiation induced acute mucositis in head and neck cancer

Protocol summary

Study aim
Prevention of acute mucositis due to radiation therapy in patients with head and neck cancer

Design
Two arm parallel group randomized clinical trial, Double-blinded

Settings and conduct
44 volunteer patients with head and neck cancer aged 18-80 years, referred to Imam Hossein Hospital or Shohada-e-Tajrish Hospital (Tehran), who are expected to undergo radiotherapy, will be included in the study according to entry criteria. Patients will be divided into two groups by simple random method. The first group will receive mocutin spray (Sumac- Rose water) and the other group will receive benzydamine hydrochloride spray.

Participants/Inclusion and exclusion criteria
Head and neck cancers and radiation therapy candidates between 18 and 80 Physical and mental ability to participate in the study Good Performance status Antiperspirants, opioids and during the study received previous radiation therapy and a history of chemotherapy in the last six months in the oral and oropharyngeal history of connective tissue diseases such as Sjِgren, rheumatoid arthritis, lupus; Liver and kidney diseases; Major depression; Diseases involving the salivary glands such as diabetes; Diseases that cause dehydration such as chronic diarrhea, weakened immune system diseases, myelosuppression, diseases that cause mouth sores. Candidiasis and oral herpes Treatment failure, need for intravenous feeding (TPN) or hospitalization before reaching a dose of 50 Gy

Intervention groups
Patients with head and neck cancer for whom radiation therapy is to be started. The control group receives benzidamine spray and the experimental group receives sumac spray

Main outcome variables
Mucositis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161024030467N2**
Registration date: **2022-01-26, 1400/11/06**
Registration timing: **prospective**

Last update: **2022-01-26, 1400/11/06**
Update count: **0**

Registration date
2022-01-26, 1400/11/06

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4408 0297
Email address
s.poshtmahi@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-04, 1400/11/15

Expected recruitment end date
2022-08-06, 1401/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Sumac spray and Benzydamine Hydrochloride

spray on prevention of radiation induced acute mucositis in head and neck cancer

Public title
Effects of Sumac spray and Benzydamine Hydrochloride spray on prevention of radiation induced acute mucositis in head and neck cancer

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Head and neck cancer patient Candidate for radiation therapy At least 2 regions of the studied areas in terms of mucositis (based on the mucositis scale) be in the field of radiation therapy Good performance status with ECOG questionnaire between 18 to 80 Willingness to participate in the study Physical and mental ability to cooperate in filling in the questionnaire

Exclusion criteria:
Mucositis grade 3 and 4 History of chemotherapy and radiation therapy in mouth or pharynx in recent six months Pregnancy use of artificial saliva use of mouthwashes Candidiasis Having oral herpes alcohol consumption smoking Consumption of drugs affecting salivary glands such as antidepressants, opioids, anti-hypertensives, antihistamines Diuretic use Suffering from diseases of the weakened immune system Dehydration-causing diseases such as chronic diarrhea Diseases that cause recurrent oral plague History of connective tissue diseases such as Sogrene, rheumatoid arthritis, lupus liver and kidney disease major depression diseases involving salivary glands such as diabetes

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Firstly, the protocol would be described to the participants. Then, they will sign written informed consent to start the trial. The investigator is not aware of Groups allocation and will examine and record the patients findings.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

Street address
Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh St., Yemen St., Shahid Chamran Highway.

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2021-08-15, 1400/05/24

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.302

Health conditions studied

1

Description of health condition studied
Oral mucositis

ICD-10 code
K12.3

ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Mucositis Mucositis

Timepoint
At the baseline, Weeks 1,2,3,4,5,6,7

Method of measurement
Examination of oral cavity

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: Mucutin spray group who use the spray 4-8 times per day from a day before the start of radiotherapy up to two weeks of end of radiotherapy or until leaving the study for any reason.

Category
Placebo

2

Description
Intervention group: Intervention group 2: benzydamine hydrochloride spray group who use the spray 4-8 times per day from a day before the start of radiotherapy up to two weeks of end of radiotherapy or until leaving the study for any reason.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Ahmad Ameri
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Mojgan Tansaz
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No. 8, Shams street, Valiasr street
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tansaz_mojgan@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ghazaleh Heydarirad
Position
Assistant Professor
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Person responsible for updating data

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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 more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable