Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of mucutin spray and Benzydamine Hydrochloride spray on prevention of radiation induced acute mucositis in head and neck cancer patients: A comparative clinical study

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 (lemon-honey spray) and the other group will receive benzydamine hydrochloride spray.

Participants/Inclusion and exclusion criteria
Head and neck cancer and radiotherapy candidate between 18 and 80 years Physical and mental ability to work Cooperation The desire to participate in the study Good Performance Status by Questionnaire at least 2 regions of the studied areas in terms of mucositis Use of alcohol, drugs that affect salivary glands such as antipsychotics, opioid and ... During the study History of radiation therapy and chemotherapy in oral or pharynx in recent six months history of connective tissue diseases such as Sogrene, rheumatoid arthritis, lupus; liver and kidney disease; major depression; diseases involving salivary glands such as diabetes; diseases causing dehydration such as chronic diarrhea, immune deficiency disorders, myelosuppression, diseases causing repeated oral aphthous A sudden change in patient's condition or illness so that the patient's predicted radiation therapy changes before reaching the 50-gram dose. Mucositis grade 3 and 4 Candidosis and oral herpes Treatment failure, requiring intravenous nutrition (TPN) or hospitalization before reaching a 50-gram dose
Pregnancy

Intervention groups
Patients with head and neck cancer who are supposed to start radiation therapy.

Main outcome variables
Radiotherapy Induced mucositis score

General information

Reason for update
End of the clinical trial recruitment and follow-up.

Acronym

IRCT registration information
IRCT registration number: **IRCT20161024030467N1**
Registration date: **2019-05-12, 1398/02/22**
Registration timing: **prospective**

Last update: **2020-08-07, 1399/05/17**
Update count: **1**

Registration date
2019-05-12, 1398/02/22

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
2019-09-01, 1398/06/10

Expected recruitment end date

2020-02-15, 1398/11/26

Actual recruitment start date

2019-09-01, 1398/06/10

Actual recruitment end date

2020-02-15, 1398/11/26

Trial completion date

2020-04-01, 1399/01/13

Scientific title

Effects of mucutin spray and Benzydamine Hydrochloride spray on prevention of radiation induced acute mucositis in head and neck cancer patients: A comparative clinical study

Public title

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

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Head and neck cancer and radiotherapy candidate age between 18 to 80 Life expectancy more than a year based on physician or team estimates Physical and mental ability to cooperate in filling in the questionnaire desire to participate in the study Good performance status with ECOG questionnaire At least 2 regions of the studied areas in terms of mucositis (based on the mucositis scale) be in the field of radiation therapy

Exclusion criteria:

Use of alcohol, drugs that affect salivary glands such as antipsychotics, opioids, antihypertensives, antihistanines, diuretics, mouthwashes and artificial saliva and cigarettes history of radiation therapy and chemotherapy in mouth or pharynx in recent six months history of connective tissue diseases such as Sogrene, rheumatoid arthritis, lupus; liver and kidney disease; major depression; diseases involving salivary glands such as diabetes; diseases causing dehydration such as chronic diarrhea, immune deficiency disorders, myelosuppression, diseases causing repeated oral aphthous Mucositis grade 3 and 4 Candidosis or oral herpes Pregnancy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done by Randomizer software, before starting the trial. Patients who have inclusion criteria, are randomly assigned into one of the two groups based on their selected number: mucutin spray or Benzydamine Hydrochloride spray. The two groups of the trial according to a previous studies and by taking into account two-sided significance level of 0.05 and power of 99%, the sample size is calculated 20 patients in each group. Considering the possibility of failure to follow up and patients' drop out, in order to increase the power of the study, the sample size is calculated 22 patients in each group to be totally 44 patients.

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

2018-07-30, 1397/05/08

Ethics committee reference number

IR.RBMU.RETECH.REC.1397.277

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
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 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
Prevention

2

Description
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
Imam Hossein Hospital, Shahid Madani St., Nezam Abad, Tehran
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
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Email
aham47@yahoo.com

2

Recruitment center
Name of recruitment center
Shohada Tajrish hospital
Full name of responsible person
Samira Azghandi
Street address
Shohada Tejarish Hospital, Shahrdari street, Tajrish Square
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Province
Tehran
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1989934148
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Email
Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Somayeh Esmaeili
Street address
No. 8, Shams street, Valiasr street
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1516745811
Phone
+98 21 8877 6027
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sesmaeili@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
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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ph.sanazy@gmail.com

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
Demographic data and the result of the clinical trial
When the data will become available and for how long
after 6 month
To whom data/document is available
researchers
Under which criteria data/document could be used
After publishing a monochrome article from a clinical trial
From where data/document is obtainable
send to researchers
What processes are involved for a request to access data/document
Send request via email
Comments