Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of Doxepin 0.5% mouthwash in comparison with Persica mouthwash on reducing the pain of oral mucositis in patients with head and neck cancer after radiotherapy and chemotherapy

Protocol summary

Study aim

investigation the effect of doxepin 0.5% mouthwash in comparison with persica mouthwash in reducing oral mucositis pain in head and neck cancer patients after radiotherapy and chemotherapy

Design

Double blind randomized clinical trial with parallel groups design of 56 patients.

Settings and conduct

This study was conducted in oncology ward of Shahid Sadoughi Hospital and Shahid Ramezanzadeh center in Yazd.The information of patients was recorded. Patients and nurses and researcher were not aware of the type of mouthwash received by patients.The patients were gargle each group of 5 cc of the solution for 1 minute.pain score, burning sensation, taste satisfaction ؛drowsiness and other side effects were recorded before the solution, 5, 15, 30, 60, 120, 240 min and 24 hours later in the Study Information Form . Every patient is allowed to use a mouthwash more than 2 times per day. the patient could use acetaminophen 500 mg (maximum 4 grams daily), not 60 minutes before and after the solution. The pain score was measured based on visual analogue scale

Participants/Inclusion and exclusion criteria

Entry requirements: Age>18 years old Patients who received more than 45 gray of radiation and had mucositis and their pain score was more than 4 on the basis of the Visual Analogue Scale Non-entry conditions: Sensitivity to TCA Taking TCA or MAOi in the last 2 weeks Candidiasis or oral herpes Open-angle glaucoma untreated Untreated urination retention in the past 6 weeks

Intervention groups

Group 1: Patients who get Persica mouthwash Group 2: Patients who get Doxepin rinse All of the patients use mouthwash to reduce pain.

Main outcome variables

Reduced mucositis pain؛ reduce analgesics use؛ improving the nutritional status of the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N1**
Registration date: **2020-03-24, 1399/01/05**
Registration timing: **retrospective**

Last update: **2020-03-24, 1399/01/05**
Update count: **0**

Registration date

2020-03-24, 1399/01/05

Registrant information

Name
behrooz heydari
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Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2018-05-05, 1397/02/15

Actual recruitment end date
2019-06-05, 1398/03/15
Trial completion date
2019-06-05, 1398/03/15

Scientific title
Investigating the effect of Doxepin 0.5% mouthwash in comparison with Persica mouthwash on reducing the pain of oral mucositis in patients with head and neck cancer after radiotherapy and chemotherapy

Public title
Effect of Doxepin rinse and Persica mouthwash in mucositis pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who received more than 45 gray of radiation and had mucositis and their pain score was more than 4 on the basis of the Visual Analogue Scale Age more than 18 years old
Exclusion criteria:
Sensitivity to TCA drugs Taking TCA or MAO inhibitors in the last 2 weeks Candidiasis infection or oral herpes Untreated open angle glaucoma Untreated urination retention in the past 6 weeks
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **56**
Actual sample size reached: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization method was used. Patients were randomly assigned to two groups by using Random.org site
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study participants, health care providers, and researcher unaware of the assigned intervention. Patients in both groups received medications in the same package.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi university of medical science
Street address
Shahid Sadoughi university of medical science, Shohadai Gomnam Blvd, Professor Hesabi Blvd
City
Yazd
Province
Yazd
Postal code
8915173149
Approval date
2017-12-09, 1396/09/18
Ethics committee reference number
IR.SSU.MEDICINE.REC.1396.200

Health conditions studied

1

Description of health condition studied
Oral mucositis
ICD-10 code
K12.33
ICD-10 code description
Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description
Reduction patient pain score
Timepoint
5, 15, 30, 60, 120, 240 minutes and 24 hours after applying mouthwash
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Persika Mouthwash, 5 cc, 3 times a day,1minute. Duration of study: 24 hours, manufactured by Poursina
Category

Treatment - Drugs

2

Description
Control group: Doxepine mouthwash 0.5%, 5cc, 3 times a day ,1minute. Duration of study: 24 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Ramezanzadeh radiation oncology center; Shahid Sadoughi hospital
Full name of responsible person
Behrooz Heydari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
Assistant professor
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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
After nonrecognition, all data can be share
When the data will become available and for how long
6 months after publication
To whom data/document is available
All of researchers
Under which criteria data/document could be used
Nothing
From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir
What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.
Comments