Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Efficacy of a zinc mouthwash in prevention of head and neck radiotherapy-induced-oral mucositis: A double-blind randomized placebo-controlled trial

Protocol summary

Study aim
Zinc mouthwash in preventing mucositis

Design
Clinical practice includes control group, and two parallel, double blinded and randomized groups.

Settings and conduct
This study is a cohort, blind, randomized controlled trial of 75 patients randomly divided into three groups of 25 controls or interventions. After random selection of patients, they will receive written consent (after explaining its content by the student) and eligible patients will be randomly assigned to one of the interventions by permutation blocks (each group is 25) Group 1: Zinc sulfate mouthwash, Group 2: Placebo mouthwash and Group III oral chlorhexidine. Each patient uses a group of mouthwashes three times a day for 6 weeks. Patients attending the study will be selected from randomly assigned patients to Radiation Clinic of Imam Ali Hospital in Bojnourd. The radiotherapist doctor who is responsible for recording the degree of mucositis and the patient as well as the student responsible for completing the questionnaires, are also unaware of the type of treatment intervention performed in relation to the patient.

Participants/Inclusion and exclusion criteria
Entry requirement: age over 18 undergoing head and neck radiotherapy excluding conditions: co-existing systematic diseases

Intervention groups
Intervention group: 1% zinc sulfate, 1% of wetting factors, surfactants, and various suppositories (methyl cellulose, hydroxypropylmethyl cellulose, xanthan gum) will be used to produce mouthwash. Control group: For the preparation of placebo mouthwash, different factors such as water, ethanol, glycerin, citric acid, methyl paraben and propylene paraben are used. Chlorhexidine mouthwash (Vi-one 0.2% CHX) is prepared as a ready-to-use preparation. Chlorhexidine mouthwash is used as a positive control.

Main outcome variables
mucositis based on clinical manifestations, severity of mucositis, pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190123042475N1**
Registration date: **2019-06-09, 1398/03/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-09, 1398/03/19**
Update count: **0**

Registration date
2019-06-09, 1398/03/19

Registrant information

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Marzieh Sahebnasagh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of a zinc mouthwash in prevention of head and neck radiotherapy-induced-oral mucositis: A double-blind randomized placebo-controlled trial

Public title
Efficacy of a zinc mouthwash in prevention of head and neck radiotherapy-induced-oral mucositis: A double-blind randomized placebo-controlled trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All the cancer patients over 18 treated by radiotherapy
Exclusion criteria:
Incidence of co-existing systematic diseases
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
After random selection, each group will be identified based on the randomized table. In order to receive one of the interventions, they are randomly divided into permutational blocks. The radiotherapist is responsible for recording the degree of mucositis and the participants will not be informed of any grouping. Also, students who are responsible for completing the questionnaires are also unaware of the type of treatment interventions The physician who is aware of the study and the type of medication will be told the method of selecting and assigning samples based on a randomized table of numbers and each group will be followed up through random selection.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study was a cohort, double-blinded, randomized controlled clinical trial And will be performed on 75 patients who will be randomly assigned to three 25-patient groups of control or intervention. After completing the preparation of the products, the first performer places mouthwashes in 120-cc glasses for one week use of the patients and identifies them with codes A, B or C. The radiotherapists who are responsible for recording the degree of mucositis and the patient will not be aware of any groupings done. Also, the student responsible for completing the questionnaire is also unaware of the type of medical interventions Given the double-blindness of the study, the treatments will be covered in form A, B, C. The doctor who is aware of the study and the type of medication, will be told the method of selecting and assigning samples based on a randomized table of numbers and each group will be followed up through random selection.
Placebo
Used
Assignment
Parallel
Other design features
This will be done for the first time in Iran.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
North Khorasan University of Medical Sciences
Street address
Faculty of Dentistry, Shahriar Blvd, next to Imam Ali Hospital, Bojnurd, Iran
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North Khorasan
Postal code
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Approval date
2019-03-16, 1397/12/25
Ethics committee reference number
IR.NKUMS.REC.1397.112

Health conditions studied

1

Description of health condition studied
oral mucositis
ICD-10 code
ICD-70
ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Creating mucositis based on clinical manifestations

(Clinical presentation), severity of mucositis based on the WHO benchmark

Timepoint

In the beginning of the study (before the onset of intervention), 1,2,3,4,5,6,7,8 weeks after commencing oral intake of zinc sulfate

Method of measurement

To test mucositis, the WHO classification system is divided into five degrees Grade 0 : None Grade 1 :Soreness + / - Erythema Grade 2 : Erythema , ulcer , patients can swallow solid diet Grade 3 : Ulcer , Extensive erythema , patients can not swallow solid diet Grade 4 : Mucositis to the extent that alimentation is not possible.

Secondary outcomes

1

Description

Patients' quality of life and complications

Timepoint

at the beginning of the study (before the onset of intervention), 1,2,3,4,5,6,7,8 weeks after commencing oral intake of zinc sulfate

Method of measurement

Quality of life will also be measured using a questionnaire used in previous studies, which measures 0 to 4:Grade 0 (Complications have no effect on daily activities), Grade 1 (Symptoms cause discomfort at least once a week)Grade 2 (symptoms interact with your daily activities more than once a week), Grade 3 (symptoms also interfere with basic activities of life)Grade 4 (symptoms are such that the patient is afraid to leave the home, leading a sharp reduction in the individual's social activities.

Intervention groups

1

Description

Intervention group: 1% zinc sulfate, surfactant, and various suppositories (methyl cellulose, hydroxypropylmethyl cellulose, xanthan gum) will be used to prepare the mouthwash. The first presenter will put the mouthwash in the 120 cc glasses for one week consumption of the patient and they use the mouthwash 3 times a day, 5 cc each time for 6 weeks.

Category

Prevention

2

Description

Control group: All components of the intervention group except zinc will be used to prepare the placebo mouthwash. The first presenter will put the mouthwash in the 120 cc glasses for one week consumption of the patient and they use the mouthwash 3 times a day, 5 cc each time for 6 weeks.

Category

Placebo

3

Description

Control group: Prefabricated Chlorhexidine mouthwash(Vi-one 0/2% CHX) will put in the 120 cc glasses for one week consumption of the patient and they use the mouthwash 3 times a day, 5 cc each time for 6 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

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Sponsors / Funding sources

1

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Full name of responsible person

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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
Bojnourd 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
Bojnourd University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available