Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

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

Protocol summary

Study aim
Effect of Poly herbal mouthwash in preventing mucositis

Design
double-blind randomized placebo-controlled clinical trial with parallel groups; The sample size: 75 patients in each group 25

Settings and conduct
This study is a double blind, randomized controlled trial of 75 patients randomly divided into three 25-patient groups of controls or interventions. Eligible patients will be randomly assigned to one of the interventions by using the standard random numbers table. Group 1: poly herbal mouthwash, Group 2: Placebo mouthwash and Group III oral chlorhexidine. Each patient consumes a group of mouthwashes three times a day for 6 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 undergoing head and neck radiotherapy Exclusion criteria: co-existing systemic diseases

Intervention groups
Intervention group 1: polyherbal mouthwash with Aloe vera gel, Chamomile extract, honey and mint, extraction and formulation will be done in pharmacognosy and pharmaceutical labs of pharmacy faculty of Mashhad Intervention group 2: Prefabricated Chlorhexidine mouthwash (Vi-one 0/2% CHX) (Rozhin Company) Control group: Placebo mouthwash, formulation will be done in pharmaceutical labs of pharmacy faculty of Mashhad The mouthwash will be poured into 120 cc glasses for one week consumption of the patient. The patients will rinse the mouthwash 3 times a day, 5 cc each time for 6 weeks.

Main outcome variables
mucositis based on clinical manifestations and severity of mucositis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190123042475N2**
Registration date: **2019-07-26, 1398/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-26, 1398/05/04**
Update count: **0**

Registration date
2019-07-26, 1398/05/04

Registrant information

Name
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 poly herbal mouthwash in prevention of head and neck radiotherapy-induced-oral mucositis: A double-blind randomized placebo-controlled trial

Public title
Effect of a poly herbal mouthwash in prevention of mucositis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All patients over the age of 18 undergoing radiotherapy
Exclusion criteria:
co-existing systemic 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
The eligible people will be assigned in to one of the following research groups, using the standard random numbers table. At first, some part of a printed paper filled with six-digit random numbers will be selected randomly. if the selected number ends in one of the following numbers of 1, 2 or 3, this code will be assigned to intervention group 1 (Herbal mouthwash); if it ends in 4, 5 or 6, it will be assigned to intervention 2 group (Chlorhexidine mouthwash); and if the mentioned number ends in 7, 8 or 9, it will be assigned to placebo group. The number zero will not be considered here. For appropriated blinding, the selection of random allocation codes and corresponding mouthwash allocations is done by a researcher from the research team who is not directly involved in the treatment team.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study was a prospective, double-blinded, randomized controlled clinical trial And will be performed on 75 patients who will be randomly assigned to three 25-patient groups of controls or intervention. After completing the preparation of the products, the principal investigator puts mouthwashes in the same 120-cc glasses for one week use of the patients and identifies them with a six-digit number. Patients, treatment team and investigator of clinical responses will not be aware of the types of interventions. At the end of the study, the principal investigator will decode the numbers of consumed mouthwashes and assign each to the appropriate group correctly.

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
Ethics Committee of North Khorasan University of Medical Sciences
Street address
Ethics Committee, Deputy of Research, Shahriar Blvd, next to Imam Ali Hospital, Bojnurd, Iran
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North Khorasan
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Approval date
2019-03-16, 1397/12/25

Ethics committee reference number
IR.NKUMS.REC.1397.113

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
clinical manifestations of mucositis

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 poly herbal mouthwash

Method of measurement
Clinical Examination

2

Description

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 poly herbal mouthwash

Method of measurement

World Health Organization classification system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: poly herbal mouthwash containing Aloe vera gel 3%, Chamomile extract 1%, honey 1.5%, oil mint 1%, will be formulated in pharmacy faculty of Mashhad. All prepared mouthwash will be poured into the 120 cc glasses for one week consumption of the patient. The patients will rinse the mouthwash 3 times a day, 5 cc each time for 6 weeks.

Category

Prevention

2

Description

Intervention group 2: chlorhexidine mouthwash with Vi-one brand (Rozhin Company) will be prepared from pharmacy. The mouthwash will be poured into the 120 cc glasses for one week consumption of the patient. The patients will rinse the mouthwash 3 times a day, 5 cc each time for 6 weeks.

Category

Prevention

3

Description

Control group: Placebo mouthwash containing water, citric acid 0.3% and vitamin C 1%, will be formulated in pharmacy faculty of Mashhad. All prepared mouthwash will be poured into the 120 cc glasses for one week consumption of the patient. The patients will rinse 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

Marzieh Sahebnasagh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Full name of responsible person

Marzieh Sahebnasagh

Position

Specialist Dentistry

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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