Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of mucoadhesive mouthwash containing saffron petal extract on prevention and improvement of clinical symptoms of radiotherapy-induced oral mucositis

Protocol summary

Study aim

Determining the effectiveness of saffron mouthwash on the management of radiotherapy-induced mucositis

Design

A double-blind, randomized, placebo-controlled clinical trial study will be performed on 40 individuals divided into two groups. Randomization will be done using the blocking method and random selection with the help of the Randomaize.com randomization site.

Settings and conduct

The study will be performed in patients referred to clinics of Mashhad University of Medical Sciences. Patients are randomly assigned medication and placebo after obtaining informed consent. Patients will use 10 ml of mouthwash in the morning and night and will be evaluated weekly by an oncologist.

Participants/Inclusion and exclusion criteria

-Inclusion criteria: Patients treated for head and neck cancer with chemoradiotherapy; Age between 18 and 70 years; Absence of serious dental problems; Absence of impacted teeth; No presence of cusps or sharp filling; Total radiation between 50 to 70 Gy during treatment; Exposure of at least half of the oral cavity to radiation; Patients should receive one of the drugs cisplatin or 5-fluorouracil in their chemotherapy diet. -Exclusion criteria: Severe infections that require antibiotics; Patients who have been allergic to any of the herbal extracts or previous radiotherapy; The inability of the patient to implement the treatment protocol; Renal failure (eGFR <50 ml / min); Liver failure (serum level 2 to 3 times higher than normal) .

Intervention groups

Placebo group: Acetaminophen 500 mg + placebo mouthwash containing distilled water and glycerin made by Mashhad University of Medical Sciences Intervention group: Acetaminophen 500 mg + mouthwash containing 1% extract of saffron petals containing distilled water and glycerin made by Mashhad University of Medical Sciences

Main outcome variables

Change in mucositis score based on World Health Organization scores

General information

Reason for update

Due to mouthwash preparation and its stability problems, the patient collection has not yet started. However, the researchers predict that patient recruitment will begin on 21/11/2024.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N6**
Registration date: **2021-06-10, 1400/03/20**
Registration timing: **prospective**

Last update: **2024-03-11, 1402/12/21**
Update count: **1**

Registration date

2021-06-10, 1400/03/20

Registrant information

Name
Vahid Reza Askari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01
Expected recruitment end date
2026-12-01, 1405/09/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of mucoadhesive mouthwash containing saffron petal extract on prevention and improvement of clinical symptoms of radiotherapy-induced oral mucositis

Public title
The effect of saffron on mucositis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients treated for head and neck cancer with chemo-radiotherapy Age between 18 and 70 years Absence of serious dental problems Absence of impacted teeth No cusp or sharp filling Total radiation is between 50 and 70 Gy during treatment Exposure of at least half of the oral cavity to radiation Patients should take one of the drugs cisplatin or 5-fluorouracil in their chemotherapy regimen.
Exclusion criteria:
Severe infections that require antibiotics. Patients who have been allergic to any of the herbal extracts or previous radiotherapy Inability of the patient to implement the treatment protocol Renal failure (eGFR <50 ml / min) Liver failure (serum level 2 to 3 times higher than normal)
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization takes place in three stages: 1- Creating a random sequence: in this stage of block randomization: quadruple blocks; Possible scenarios for two groups of experiment: Six quadruple modes including: 1- AABB, 2- ABAB, 3-BBAA, 4-BABA, 5-BAAB and 6- ABBA Possible scenarios for two groups of 20 equal to 10 = 4/40 Randomly write 10 blocks (using a table of random numbers) Write the final equivalent block Coding and allocating patients to receive medicine or placebo after opening the envelopes from number 1 to number 40, respectively. 2- Hide random allocation, which is done in the form of coded boxes with the random sequence with the help of random numbers table. In this method, a number of boxes of the same shape and size are numbered in random order and contain a medicine or placebo that have exactly the same regarding the appearance. 3- Execution of random allocation process: - The person who creates the random sequence: statistics consultant - The person who evaluates and registers the participants in terms of inclusion and exclusion criteria: Student of the project - The person who assigns the participants to the groups: Oncologist
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the use of placebo similar to the intervention treatment, the physician associated with the participants and participants will not be informed of the assigned treatment. Also, the analyst will be unaware of the treatment assigned to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A and B. The placebo will be very similar in treatment in terms of shape, consistency, packaging, and smell.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street
City
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Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-09-22, 1399/07/01
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.452

Health conditions studied

1

Description of health condition studied

Radiotherapy-induced oral mucositis

ICD-10 code

K12.33

ICD-10 code description

Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description

Change in mucositis score based on World Health Organization scoring

Timepoint

Every week from the beginning of the drug (week zero) to the end of the study (week seven)

Method of measurement

World Health Organization mucositis scoring questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receiving routine treatment (Acetaminophen 500 mg three times a day, Made by Jalinous company) + placebo mouthwash containing distilled water and glycerin twice a day made by Mashhad University of Medical Sciences

Category

Placebo

2

Description

Intervention group: Receiving routine treatment (Acetaminophen 500 mg three times a day, Made by Jalinous company) + Mouthwash containing 1% extract of saffron petals and distilled water and glycerin twice day made by Mashhad University of Medical Sciences

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Dr Vahid Reza Askari

Street address

Mashhad University of Medical Science, Azadi Square

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Vahid Reza Askari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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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