Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of saffron extract with artificial saliva on alleviation of oral mucositis caused by head and neck radiotherapy: a randomized trial

Protocol summary

Study aim
Comparing the effectiveness of saffron extract with artificial saliva spray on the relief of oral mucositis caused by radiotherapy in the head and neck region.

Design
2 intervention and control groups with double-blind parallel groups, randomized, on 62 patients

Settings and conduct
Medical centers of Qom in the field of radiotherapy. Patients use the desired drug for 4 weeks and the results are recorded and reviewed by the main researcher. The principal investigator and statistical consultant are blinded. Only the clinical caregiver and the patient know the type of medicine.

Participants/Inclusion and exclusion criteria
People's consent to conduct a trial of male and female patients in the age group of 18-60 years with head and neck cancers undergoing radiotherapy in Qom treatment centers who have received at least 36-40 Gy of radiation [34] and at least 4 weeks from the start of their radiotherapy treatment is over. No allergy to saffron and no heart disease and blood pressure Criteria for not entering the study: suffering from other oral and dental diseases. Long-term use of anti-coagulant and anti-platelet drugs, pregnancy and breastfeeding, diabetes, blood pressure, autoimmune diseases, GVHD, use of saliva-reducing drugs, alcohol use, drug addiction, bone marrow transplant, active lesion, oral infection and mucosal wounds before starting radiotherapy

Intervention groups
The first group: the treatment group receiving common treatments to prevent mucositis plus receiving a daily puff of saffron, which is equivalent to 100 mg of saffron. After using the spray, patients do not wash their mouths and do not eat food for thirty minutes. The second group: recipients of the usual mucositis treatments plus artificial saliva spray (mucosamine) which is entirely at the expense of the project manager.

Main outcome variables
Reducing the severity of mucositis and patient pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221207056743N1**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date
2023-03-29, 1402/01/09

Registrant information

Name
Fateme Zahra Shafiee

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
2023-04-09, 1402/01/20

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of saffron extract with artificial saliva on alleviation of oral mucositis caused by head and neck radiotherapy: a randomized trial

Public title
Comparison the effect of saffron extract with artificial saliva on alleviation of oral mucositis caused by head and neck radiotherapy: a randomized trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People's satisfaction with the trial Patients with head and neck cancers undergoing radiotherapy Have received at least 36-40 Gy of radiation At least 4 weeks have passed since the start of their radiotherapy treatment. Not allergic to saffron Absence of heart diseases and blood pressure
Exclusion criteria:
Suffering from other oral and dental diseases. Long-term use of anti-coagulant and anti-platelet drugs. Systemic conditions such as pregnancy and breastfeeding, diabetes, hypertension, autoimmune diseases, GVHD, use of saliva reducing drugs, alcohol use, drug addiction, bone marrow transplantation, active lesion, oral infection and mucosal wounds before starting radiotherapy Lack of consent to continue the trial and lack of consent to continue the treatment. Performing any surgery and trauma Suffering from any heart, liver and kidney failure and any disease that has manifestations similar to oral mucositis.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (https://www.sealedenvelope.com). Allocation concealment is also guaranteed due to the use of special codes generated by the website
Blinding (investigator's opinion)
Double blinded
Blinding description
The treating physician and the statistical analyst are unaware of the allocation of the type of treatment to the patients, and the information is collected by a researcher outside the treatment and statistics team in the form of coding.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
No. 83, Shahid Lotfi Niaser (Alley No. 4), Jahad Daneshgahi alley, Safashehr St.
City
Qom
Province
Ghoum
Postal code
3716993456
Approval date
2023-01-30, 1401/11/10
Ethics committee reference number
IR.MUQ.REC.1401.229

Health conditions studied

1

Description of health condition studied
Oral mucositis
ICD-10 code
C00-D48
ICD-10 code description
سرطان ها

Primary outcomes

1

Description
Oral mucositis score
Timepoint
Start time, day 7،14،21،28
Method of measurement
WHO definition of oral mucositis grading: 0_none 1_pain and redness 2_redness, wound, ability to eat solid foods

3_wound, need for liquid diet 4_feeding impossible

2

Description
Pain sevirity
Timepoint
Start time, day 7،14،21،28
Method of measurement
Pain Visual analogue scale

3

Description
Teeth color
Timepoint
Starting day and day 28
Method of measurement
Vita shade guide

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the group receiving common treatments to prevent mucositis plus receiving a daily puff of saffron, which is equivalent to 100 milligrams of saffron with a concentration of 1%. After using the spray, patients do not wash their mouths for thirty minutes and do not eat They don't eat either. The duration of use is 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: recipients of usual mucositis treatments plus a daily puff of mucosamine artificial saliva spray. The duration of use is 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital, Qom
Full name of responsible person
Hoda Abolhasani
Street address
Shahid Beheshti Boulevard, Azadegan Square, Qom
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3719964797
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mustafa Vahidian
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Qom University of Medical Sciences and Healthcare Services, Shahid Lavasani St. (Saheli), Qom
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Email
30006207@email.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum University of Medical Sciences
Proportion provided by this source
80
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
Ghoum University of Medical Sciences
Full name of responsible person
Fatemeh Zahra Shafiee
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Position
Academic staff

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No further information exists

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available