Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of an oral topical pomegranate peel (Punica granatum) product in prevention of acute radiation-induced oral mucositis in patients with head and neck cancer: A pilot study

Protocol summary

Study aim

Evaluation of efficacy of an oral topical pomegranate peel (Punica granatum) product in prevention of acute radiation-induced oral mucositis in patients with head and neck cancer

Design

A clinical trial with a control group, parallel groups, double-blind, and randomized.

Settings and conduct

Sixteen volunteer patients with head and neck cancer, aged between 18 and 75 years, referred to Shahid Tajrish Hospital (Tehran), who are about to start radiotherapy, will be enrolled in the study based on the inclusion and exclusion criteria and will be randomly assigned into two groups. The first group will receive the oral topical pomegranate peel product (intervention group), and the second group will receive a placebo (control group). Patient recruitment will continue until the sample size is complete in both groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of head and neck cancers based on pathology. Candidate for radiotherapy of head and neck regions. Presence of at least two areas showing mucositis (based on mucositis assessment criteria) within the radiotherapy field. Age between 18 and 75 years. Exclusion Criteria: History of allergy to pomegranate. Presence of infectious and recurrent oral lesions. Dental diseases. Use of alcohol or medications affecting salivary glands, such as antidepressants and opioids. Liver and kidney diseases. Diabetes. Diseases causing dehydration, such as chronic diarrhea.

Intervention groups

The intervention and control groups will use, respectively, the oral spray containing pomegranate peel extract and the placebo product every four hours, six puffs each time, starting one day before the initiation of radiotherapy and continuing until two weeks after its completion or until the patient withdraws from the study for any reason.

Main outcome variables

Mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240607062030N1**
Registration date: **2025-04-24, 1404/02/04**
Registration timing: **prospective**

Last update: **2025-04-24, 1404/02/04**
Update count: **0**

Registration date

2025-04-24, 1404/02/04

Registrant information

Name

Maryam Jahandideh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 0052

Email address

drjahandideh@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-11-06, 1404/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of an oral topical pomegranate peel (Punica granatum) product in prevention of acute radiation-induced oral mucositis in patients with head and neck cancer: A pilot study

Public title

Effects of a pomegranate peel oral products on the prevention of oral mucositis induced by radiation therapy in head and neck cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with head and neck cancer based on pathology Candidate for head and neck radiotherapy The presence of at least two examined areas for mucositis (based on the mucositis assessment criteria) within the radiotherapy field Age between 18 and 75 years

Exclusion criteria:

History of allergy to pomegranate Presence of recurrent or infectious oral lesions Presence of dental diseases Liver and kidney diseases. Use of alcohol or medications affecting the salivary glands, such as antidepressants and opioids. Diagnosis of diabetes Diseases causing dehydration, such as chronic diarrhea History of connective tissue diseases such as Sjögren's syndrome, rheumatoid arthritis, and lupus.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign individuals into two groups of 10, we first number them from 1 to 20 and then use SAS 9.1 software to randomly allocate them into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The pomegranate peel product and the placebo are placed in identical bottles in terms of appearance, and neither the researcher nor the patients are aware of their contents.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Department of Pharmaceutical Sciences,Tehran Islamic Azad University of Medical

Street address

Islamic Azad University of Pharmaceutical Sciences Branch., Yakhchal Ave., Dr Shariati Ave., Gholhak

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2024-01-06, 1402/10/16

Ethics committee reference number

IR.IAU.PS.REC.1402.555

Health conditions studied

1

Description of health condition studied

Radiation-induced oral mucositis

ICD-10 code

K12.33

ICD-10 code description

Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description

Mucositis

Timepoint

Before intervention and the first to fifth weeks of radiotherapy and two weeks thereafter

Method of measurement

Clinical examination of seven areas of the oral cavity, questioning the patient using the VAS (Visual Analogue Scale).

Secondary outcomes

empty

Intervention groups

1

Description
Invention group: The oral spray containing pomegranate peel extract will be used every four hours, six puffs each time, starting one day before the initiation of radiotherapy and continuing until two weeks after its completion or until the patient withdraws from the study for any reason.

Category
Prevention

2

Description
Control group: The placebo oral spray will be used every four hours, six puffs each time, starting one day before the initiation of radiotherapy and continuing until two weeks after its completion or until the patient withdraws from the study for any reason.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Dr. Ghazaleh Heydarirad

Street address
Shahrdari Street,Tajrish Sqr, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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Islamic Azad University of Pharmaceutical Sciences Branch., Yakhchal Ave., Dr Shariati Ave., Gholhak.,

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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
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Reza sayari

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Full name of responsible person
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Latest degree

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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

There is no more information

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