

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Investigating the effect of pomegranate flower syrup in preventing severe mucositis caused by radiotherapy after head and neck cancer surgery

Protocol summary

Study aim

We evaluate the clinical effects of pomegranate syrup to prevent complications of mucositis caused by radiotherapy.

Design

A controlled, parallel-group, double-blind, randomized, phase two clinical trial on 120 patients. The rand function of Excel software is used for randomization

Settings and conduct

The place of the cancer institute is Imam Khomeini Hospital in Tehran. Patients do not have information about the type of syrup received. Also, the researcher does not have information about the type of syrup received by the patient. The pharmacist delivers the medicine to the patient. The shape of the drug and placebo are similar, and pharmacists know about the type of syrup based on the code

Participants/Inclusion and exclusion criteria

Candidates for at least 50 Gy radiotherapy to the oral cavity with or without concurrent chemotherapy will be included in the study. Also, patients who had a history of head and neck radiotherapy, opium addiction or methadone use, active mucosal disease in the radiotherapy area and people under 18 years of age are excluded from the study.

Intervention groups

The first group is the control group, which includes 60 patients who receive placebo in the amount of 10 cc 3 times a day. The second group, the intervention group, includes 60 patients who receive pomegranate flower mouthwash in the amount of 10 cc 3 times a day.

Main outcome variables

Mucositis grade; Gender; Concurrent chemotherapy; Age; Weight.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221028056330N1**

Registration date: **2023-02-02, 1401/11/13**

Registration timing: **prospective**

Last update: **2023-02-02, 1401/11/13**

Update count: **0**

Registration date

2023-02-02, 1401/11/13

Registrant information

Name

Fatemeh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 2529 0859

Email address

dr.fatemeh.samadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2025-03-18, 1403/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of pomegranate flower syrup in preventing severe mucositis caused by radiotherapy after head and neck cancer surgery

Public title

Effect of pomegranate flower syrup in preventing mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The study of patients with head and neck cancers who are candidates for at least 50 Gy radiotherapy to the oral cavity with or without concurrent chemotherapy after surgery will be included in the study.

Exclusion criteria:

Patients who had a history of head and neck radiotherapy, opium addiction or methadone use, active mucosal disease in the radiotherapy area and people under 18 years of age are excluded from the study.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using coded boxes with a random sequence In this method, a number of boxes or cans that are numbered based on a random sequence are used. In these boxes, drugs or sheets with random allocation are used. If researchers use this method, they should make sure that the boxes are sealed enough, their appearance is similar, and their weight is the same. In this study, the drug container and the placebo have a clear similarity, and neither the researcher nor the patient knows about it.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not know about the type of syrup received The researcher also has no information about the type of syrup received by the patient The pharmacist only knows about the syrup received by the patients and delivers the medicine to the patients

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Intersection of Quds St, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

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Approval date

2022-08-30, 1401/06/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.165

Health conditions studied

1

Description of health condition studied

Mucositis caused by radiotherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of mucositis according to who definition.

Timepoint

Checking the severity of mucositis every week during radiotherapy

Method of measurement

Based on the definition of the severity of mucositis of the World Health Organization. Severity of mucositis based on who definition. Zero grade: The patient has no symptoms. Grade 1: Erythema and mouth burning (brief mucosal inflammation) Grade 2: Erythema and oral ulcers that still have the ability to eat solid foods. (Mild pain that requires painkillers.) Grade 3: Ulcers with extensive erythema who cannot swallow solid food. (Severe pain that requires strong pain relief) Grade 4: Mucositis has become very widespread and has made feeding completely impossible for the person, and at the same time that there is a need for hospitalization for him.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Including 60 patients who receive pomegranate flower mouthwash in the amount of 10 cc 3 times a day. To prepare the product, firstly, pomegranate flower is procured from the medicinal plant market of Iran and a herbarium code is assigned to it by a botanist. To prepare 240 cc of pomegranate flower syrup, dissolve 8 grams of hydroalcoholic extract (70 degrees) prepared by maceration method and dried by rotary machine and vacuum in some distilled water, then add xylitol (sweetener) and methyl paraben (preservative). We add the volume of the solution with distilled water. We increase the pH of the placebo syrup to 240 cc. Finally, if needed, the viscosity-increasing and regulating agent isylitol is made as a sweetener and methyl paraben as a preservative, and the food coloring is used to match its color with pomegranate flower syrup. Standardization of syrup is done by determining the amount of total phenolic compounds through Folin Cicalto test, and gallic acid is used as a standard. The microbial control of the syrup is also done to ensure that the count of microorganisms is within the permissible limits of the pharmacopoeia. Patients undergo weekly visits from the first day of treatment to the end of radiotherapy for a total of 6-7 weeks.

Category

Treatment - Drugs

2

Description

Control group: 60 patients who receive placebo in the amount of 10 cc 3 times a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute, Tehran Imam Khomeini Hospital

Full name of responsible person

Fatemeh samadi

Street address

Cancer Institute, Imam Khomeini Hospital, Qarib Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr reza ghailethaki

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

fatemeh samadi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The published information is related to the effect of pomegranate flower syrup in preventing mucositis and its effect on patient nutrition and weight gain

When the data will become available and for how long

The access period is expected to start from 1404

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

After completing the research, the data can be used for non-employees in the institutions as well.

From where data/document is obtainable

Email the following address to receive information and documents dr.fatemeh.samadi@gmail.com

What processes are involved for a request to access data/document

After the completion of the research and data analysis, and considering that the patient is admitted until the end of 1403, the second six months of 1404, information and files can be accessed.

Comments