

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of mouth wash pomegranate seed extracts on improving oral mucositis in patients treated with chemotherapy

Protocol summary

Study aim

Determination of the effect of mouthwash extract of pomegranate seed on the improvement of stomatitis in patients undergoing chemotherapy

Design

The group of routine mouthwash and group of routine mouthwash added Pomegranate extract.

Settings and conduct

Chemotherapy ward

Participants/Inclusion and exclusion criteria

This double-blind clinical trial study was conducted in Kashan, Iran in 2018, undergoing chemotherapy and suffering from oral stomatitis and treated with an anti-inflammatory drug.

Intervention groups

To all patients after admission are given gloomy bottles of mouth wash solution . experimental group containing pomegranate extract + lidocaine 2%, Al-mg-s syrup, diphenhydramine syrup, nystatin drop, diphenhydramine syrup (glass 1), and solvent control group A routine ampoule of lidocaine 2%, Al-mg-s syrup, diphenhydramine syrup, nystatin drop, daphenhydramine syrup.

Main outcome variables

Severity of degree of stomatitis

General information

Reason for update

Acronym

Pomegranate seed extract and stomatitis

IRCT registration information

IRCT registration number: **IRCT20100829004655N10**

Registration date: **2018-09-17, 1397/06/26**

Registration timing: **prospective**

Last update: **2018-09-17, 1397/06/26**

Update count: **0**

Registration date

2018-09-17, 1397/06/26

Registrant information

Name

Mohsen Taghadosi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mouth wash pomegranate seed extracts on improving oral mucositis in patients treated with chemotherapy

Public title

Effect of pomegranate seed extract on the improvement of stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing chemotherapy Having consciousness Age above 18 years old Satisfaction with participation in the study Non-allergenic to herbal products

Exclusion criteria:

Getting radiotherapy during research Fever Use of other mouthwashes other than mouthwashes defined in this study The patient's decision to withdraw from the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Cancer patients who are continually referred to randomly assigned block randomization based on a computer spss program will be divided into two groups: intervention and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients have no information about the kind of consultation that receive

Placebo

Used

Assignment

Parallel

Other design features

In this study, the following people were blind and did not know of the content two glass: 1) the person who gave the glass to the patients and examine the patients' oral mucosa 2) patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

kashan University of Medical Sciences , Km 5 ghotb Radvandi Blvd.

City

Kashan

Province

Isfahan

Postal code

87159/81151

Approval date

2018-07-30, 1397/05/08

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.032

Health conditions studied

1

Description of health condition studied

Stomatitis

ICD-10 code

k12.1

ICD-10 code description

Stomatitis

Primary outcomes

1

Description

stomatitis

Timepoint

Before intervention, days 1, 7 and 14 after intervention

Method of measurement

Standardized checklist stomatitis WHO

Secondary outcomes

1

Description

Change grade of stomatitis

Timepoint

Before intervention, days 1, 7 and 14 after intervention

Method of measurement

Standardized checklist stomatitis WHO

Intervention groups

1

Description

The intervention group use solution of routine + Pomegranate seed extract, each 100 cc containing lidocaine 2%, 50 mg (2.5.2 cc), 6 cc nystatin drop, Al-mg-s syrup 27.5 cc, Diphenhydramine 14 cc and 50 cc syrup of extract Pomegranate seed (50 to 50%) 4 times a day, for 14 days after breakfast, lunch, dinner, and before bed, 15 cc each time and keep it for 3 minutes, then These patients should not wash their mouths and give them an hour to eat food. Considering the two-sidedness of the study, oral mucosa on the first, seventh and fourteenth days by a nurse trained in the ancology department who does not know the mouthwash solution and then checklist is completed .

Category

Treatment - Drugs

2

Description

Control group: Routine mouthwash (lidocaine 2% 100 mg (5 cc), 12 cc nystatin drop, AL-mg-s 55 cc, diphenhydramine syrup 28 cc) 4 times a day, for 14 days after breakfast, lunch, Dinner, and before bed, 15 cc each time and keep it for 3 minutes. Then they should be discarded. These patients should not wash their mouths and give them up to one hour of food intake, and according to double-blind In the study, the oral mucosa on the first, seventh and fourteenth days is checked by the nurse in the oncology nurse who is unaware of the type of mouthwash and the checklist is completed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti medical education Center of Kashan university of medical Sciences

Full name of responsible person

Taghadosi Mohsen

Street address

Kashan University of Medical Sciences , Arctic Blvd Ravandi-

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Gholamali

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

Position

Ph.D, Faculty member Assistant professor, director of journal pheyz-Head of Nursing and Midwifery Fac

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

Position

ph.D, Faculty member Assistant professor, director of journal pheyz, Head of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fahimeh Ganjoori

Position

MSc Student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only available to scholars working in academia and academia

Under which criteria data/document could be used

If you observe trust and mention the source, the data can be used by researchers

From where data/document is obtainable

Send the following e-mail to the following address: taghadosi_m@Kaums.ac.ir

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

After receiving the letter via email, your request will be reviewed within 2 weeks, and the data will be sent to the applicant at the discretion.

Comments