Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of mouthwash solution contaning marshmallow root extract and routine solution on improvement chemotherapy induced stomatitis

Protocol summary

Study aim
Comparing the effect of mouthwash solution contaning marshmallow root extract and routine solution on improvement chemotherapy induced stomatitis

Design
the group of routine mouth wash and group of "mouthwash solution" added to routine mouth wash

Settings and conduct
chemotherapy ward

Participants/Inclusion and exclusion criteria
The study population consisted of all cancer patients with oral stomatitis and under chemotherapy treatment with an anti-inflammatory and referred to Shahid Beheshti Medical Center, Kashan, Iran

Intervention groups
To all patients after admission, are given gloomy bottles of mouth wash solution (that experimental mouth wash solution contain:lidocaine2%,syrp Al-mg-s,syrp Diphenhydramine and aqueous extract of the Marshmallow root 8%.(glass-1)and the routine solution (lidocaine2%, Diphenhydramine and Al-mg-s surup,and Nystatin drop)(glass-2)

Main outcome variables
pain severity (VAS) stomatitis stage (according to WHO)

General information

Reason for update

Acronym
Marshmallow root and ostomatitis

IRCT registration information
IRCT registration number: **IRCT201307274655N4**
Registration date: **2016-07-14, 1395/04/24**
Registration timing: **prospective**

Last update: **2018-03-01, 1396/12/10**
Update count: **1**

Registration date
2016-07-14, 1395/04/24

Registrant information

Name
Mohsen Taghadosi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2016-08-22, 1395/06/01

Expected recruitment end date
2016-11-20, 1395/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of mouthwash solution contaning marshmallow root extract and routine solution on improvement chemotherapy induced stomatitis

Public title
Effect of mouth wash contaning marshmallow root extract on improvement stomatitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

undergoing chemotherapy age above18 years old having consciousness

Exclusion criteria:

Age

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

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

sequential patient discharge allocated in 2 group in this study: intervention and control group by computer randomize program (spss)

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 contents two glass: 1) The person who gave the glass to the patient and examine the patient 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- Ghotb Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

87159/81151

Approval date

2016-06-01, 1395/03/12

Ethics committee reference number

IR.KAUMS.REC.1395.10

Health conditions studied

1

Description of health condition studied

Stomstitis

ICD-10 code

K12.1

ICD-10 code description

Stomatitis and related lesions

Primary outcomes

1

Description

ostomatitis

Timepoint

Before and seventh and fourteenth days after the intervention

Method of measurement

Standardized checklist stomatitis WHO

Secondary outcomes

1

Description

Change grade of stomatitis

Timepoint

Beforebefore and seventh and fourteenth days after the intervention

Method of measurement

Standardized checklist stomatitis WHO

Intervention groups

1

Description

The intervention group use solution of routine mouthwash plus hydro alcholic extract of marshmallow root that each 100m.l of that contains :lidocaine 2% 50 mg ,Al-mg-s syrup 25 ml,Diphen hydramine surp12.5cc(31.25mg) and 60 cc hydro alcholic marshmallow extract root 8% (glass 1).Patients 4 times a day, after breakfast, lunch, dinner and before sleeping, first, wash their hands, cleaning teeth with a soft toothbrush and one type of toothpaste, then 15 cc of the solution kept for 3 min in their mouth and then throw away. Patients should not wash their mouth, and refrain from consuming food until one hour after. oral mucosa patients on the first, seventh and fourteenth days after getting mouthwash checked by a oncology nurse who does not know the mouthwash solution and then checklist is completed.

Category

Treatment - Drugs

2

Description
Control group use routine mouthwash solution that100 ml of that containing :lidocaine 2%100mg, Al-mg-s syrup55 ml , Diphenhydramine syrup 28 cc(70mg),nystatin dpop1,200,000 unit(12cc)(glass 2).Patients 4 times a day, after breakfast, lunch, dinner and before sleeping, first, wash their hands, cleaning teeth with a soft toothbrush and one type of toothpaste, then 15 cc of the solution kept for 3 min in their mouth and then throw away. Patients should not wash their mouth, and refrain from consuming food until one hour after.oral mucosa patients on the first, seventh and fourteenth days after getting mouthwash checked by a oncology nurse who does not know the mouthwash solution and then 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
Taghadsi Mohsen
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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
Hamidi 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
Vice President of Research of Kashan University of Medical Sciences
Full name of responsible person
Taghadosi Mohsen
Position
PhD -Faculty member Assistant professor -director of journal pheyz Department,Head of medical-surgic
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Faculty of Nursing & Midwifery,Kashan University of Medical Sciences

Full name of responsible person

Taghadosi Mohsen

Position

PhD -Faculty member Assistant professor -director of journal pheyz Department,Head of medical-surgic

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

ghorbani vadeghani Mohamadsadegh

Position

MSc Student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Web page address

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 the trust and mention the source, data is available for 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