Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparing the effect of mouth wash containing yarrow plant extract and routine solution on improvement stomatitis in cancer patients receiving chemotherapy

Protocol summary

Summary

The purpose of this study is to investigate the effect of mouth wash containing yarrow plant extract on improvement stomatitis due chemotherapy. Double blind clinical trial study is conducted in cancer patients admitted to Shaheed Beheshti Hospital with oral stomatitis and under chemotherapy treatment with an anti-inflammatory drugs. In this study; patient, the nurse examined mouth the patient and give mouthwash solution to the patient were not aware from the content of the solution. Inclusion criteria: informed consent for participation in the study, aged 20 years and older, not receive radiation therapy after diagnosis, not use another mouthwash solution during the study, not receiving systemic antibiotics and antifungals. In this study participants will exclude if they are using irregular (amount, frequency) mouthwash and they cannot tolerate the smell of a solution containing yarrow extract. In this study, 42 patients were selected by convenience sampling with table of random numbers; severity of stomatitis in experimental and control groups is similar. To all patients after admission, are given extract yarrow+ routine solution (glass 1 (experimental)) and the routine solution (lidocaine , dexamethasone, sucralfate, diphenhydramine) (glass 2(control)). 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. According to a double blind study, oral mucosa patients on the first, seventh and fourteenth days after getting mouthwash checked by a nurse working in oncology ward who does not know the mouthwash solution and then checklist is completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092214729N1**
Registration date: **2013-12-31, 1392/10/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-31, 1392/10/10

Registrant information

Name

Leyla Soleymanpoor

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33 4635 2622

Email address

miranzadeh_s@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-10-01, 1392/07/09

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of mouth wash containing yarrow plant extract and routine solution on improvement stomatitis in cancer patients receiving chemotherapy

Public title
Effect of mouth wash containing yarrow plant extract on improvement stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: informed consent for participation in the study, aged 20 years and older, no underlying disease (allergy, allergic rhinitis, asthma), not receive radiation therapy after diagnosis, having consciousness, not use another mouthwash solution during the study, and not receiving systemic antibiotics and antifungals. Exclusion criteria: receiving radiotherapy during treatment, fever, use from another solution mouthwash during the study, the decision to withdraw from the study, irregular use of mouthwash solution (frequency, amount), solution containing extract yarrow odor intolerance by patients and received systemic antibiotics and antifungals at the beginning or during the study.

Age
From **1 year** old to **149 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, the following people were blind and did not know of the contents two glass (glass 1: extract yarrow + 2 dexamethasone 8 mg, 5 tablets sucralfate 500 mg, 1 syrup diphenhydramine 12.5 mg, 1 injection of lidocaine 2% and glass 2: 2 dexamethasone 8 mg, 5 tablets sucralfate 500 mg, 1 syrup diphenhydramine 12.5 mg, 1 injection of lidocaine 2%) . 1) The person who gave the glass to the patient 2) A person who has examined the oral mucosa. 3) Patients

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Ghotb Ravandi Blvd

City
Kashan

Postal code
88141/87159

Approval date
2013-09-30, 1392/07/08

Ethics committee reference number
2571/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Stomatitis

ICD-10 code
k12.1

ICD-10 code description
Stomatitis and related lesions

Primary outcomes

1

Description
Stomatitis

Timepoint
Before and seventh and fourteenth days after the intervention

Method of measurement
Standardized checklist stomatitis WHO

Secondary outcomes

empty

Intervention groups

1

Description
Case 1: a experimental group solution containing extract yarrow-routine solution (2 dexamethasone 8 mg, 5 tablets sucralfate 500 mg, 1 syrup diphenhydramine 12.5 mg, 1 injection of lidocaine 2%) (glass 1) is given will. 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. According to a triple blind study, 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

Case 2: a control group routine solution containing (2 dexamethasone 8 mg, 5 tablets sucralfate 500 mg, 1 syrup diphenhydramine 12.5 mg, 1 injection of lidocaine 2%) (glass 2) is given will. 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. According to a triple blind study, 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

Shaheed Beheshti Hospital of Kashan University of Medical Sciences

Full name of responsible person

Leyla Soleymanpoor

Street address

Kashan University of Medical Sciences

City

Kashan

2

Recruitment center

Name of recruitment center

Shaheed Beheshti Hospital of Kashan

Full name of responsible person

Sedigheh Miranzadeh

Street address

Nursing Faculty, Kashan University of Medical Sciences

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholam ali Hamidi, Vice chancellor for research, Kashan University of Medical Sciences

Street address

Vice chancellor for research, Kashan University of Medical Sciences

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Leyla Soleymanpoor

Position

Graduate student

Other areas of specialty/work

Street address

Kashan University of Medical Sciences

City

Kashan

Postal code

87155/111

Phone

+98 33 4635 2622

Fax

Email

Leylalegla@yahoo.com

Web page address

www.kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Sedigheh Miranzadeh

Position

Master of Science
Other areas of specialty/work
Street address
Kashan - Ghotb Ravandi Blvd.
City
Kashan
Postal code
81755/111
Phone
+98 36 1555 2999
Fax
Email
S_Miranzadeh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Leyla Soleymanpoor
Position
Graduate student
Other areas of specialty/work
Street address
Kashan - Ghotb Ravandi Blvd.
City
Kashan
Postal code
87155/111
Phone
+98 36 1555 2999
Fax
Email
Leylalegla@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty