

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Study of the effect of the combined mouthwash (dalen) on treatment of stomatitis in patient undergoing chemotherapy

Protocol summary

Study aim

Determination of the effect of dalen mouthwash on incidence and treatment of stomatitis in patient undergoing chemotherapy

Design

Clinical trial with community-based and pragmatic control group with parallel binary blind groups, randomly blocked using six rows of four-row blocks with 22 individuals in each group. Patients are hospitalized one day before chemotherapy and their mouth is evaluated after admission. The solution used for the combined oral mucosal solution test group (drops of 12 nittine / 100 ml diphenhydramine syrup / and 250 ml of plum opioid 240 ml) was used in the placebo group (sterile water solution and a color similar to that of soluble solution Has a neutral effect). At day zero (one day before starting chemotherapy), the seventh day after chemotherapy and the 14th day after chemotherapy in the two groups of patients will be examined by a researcher and one assistant.

Settings and conduct

The research area is adult hematology and adult hematology located in Ahvaz Shafa Hospital.

Participants/Inclusion and exclusion criteria

* Inclusion criteria: 1.All patients with acute lymphoma and acute leukemia in the range of 18-68 years old who are referred to the Department of Advanced Hematology, Ahvaz Shafa Hospital, who get chemotherapy. 2. Have acute leukemia and lymphoma cancers under periodic chemotherapy. 3. When entering the study, there is no stomatitis. * Exit criteria: Radiation therapy is also associated with chemotherapy.

Intervention groups

Intervention in this study involves the use of a combined mouthwash Dalen (Nystatin drops 12 ml / diphenhydramine syrup 100 ml / aluminum jig 240 ml) In the test group and using a sterile water solution and a colored substance(Similar to the color of the solution that has neutral effects) In the placebo group.

Main outcome variables

Occurrence of stomatitis, Severity of stomatitis, recovery time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037737N2**

Registration date: **2018-07-06, 1397/04/15**

Registration timing: **prospective**

Last update: **2018-07-06, 1397/04/15**

Update count: **0**

Registration date

2018-07-06, 1397/04/15

Registrant information

Name

sedighe ghobadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effect of the combined mouthwash (dalen) on treatment of stomatitis in patient undergoing chemotherapy

Public title
The effect of combined mouthwash on chemotherapy-induced ulcer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Have acute leukemia and lymphoma cancers and are undergoing periodic chemotherapy. When entering the study, there is no have stomatitis.
Exclusion criteria:
Having asthma and other allergic diseases Radiation therapy is also associated with chemotherapy. During the study, they develop a systemic infection.

Age
From **18 years** old to **68 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Blocks (one per group): Patients will be divided into two groups, the case (22 recipients of combined mouthwash) and control (22 patients taking placebo). The division of selected subjects will be done randomly in blocks of study using quadrilateral blocks. The division of selected subjects will be done in randomized blocks using six rows of four blocks (ABAB-BABA-ABBA-BAAB-AABB-BBAA). Combination mouthwash (A) and placebo group (B).

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients and the nurses caring the patients and the researchers did not know which groups were included in each group and which drug was used in each group, therefore, a double blind study will be conducted.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

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Golestan. Ahvaz, IRAN.

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ahvaz

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Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.AJUMS.REC.1396.722

Health conditions studied

1

Description of health condition studied

Palliative care

ICD-10 code

Z51.5

ICD-10 code description

Encounter for palliative care

Primary outcomes

1

Description

Occurrence of osteomathitis in patients undergoing chemotherapy

Timepoint

On day one, seventh and fourth sessions in two groups after intervention

Method of measurement

Nominal(was observedwas not observed)

2

Description

Severity of osteomathia in patients undergoing chemotherapy

Timepoint

On day one, seventh and fourth sessions in two groups after intervention

Method of measurement

There is no wound in the first degree. The second grade involves wound healing, but the person has the ability to eat. Grade 3 is large (more than 25% of the mouth level), and the individual has only the ability to eat the Maya..

In grade 4, hemorrhagic fever is bleeding and the patient is unable to receive the substance.

3

Description

Treatment time of osteomyelitis in patients undergoing chemotherapy

Timepoint

On day one, seventh and fourth sessions in two groups after intervention

Method of measurement

based on the time of recovery symptoms of time-to-day

Secondary outcomes

1

Description

Gum wound healing

Timepoint

On day one, seventh and fourth sessions in two groups after intervention.

Method of measurement

proportional

Intervention groups

1

Description

Intervention group: Intervention group: Using a combination of mouthwash (Dilute Nitatin 12 ml / Diphenhydramine 100 ml Syrup / Aloe Minim MJ 240 ml)

Category

Rehabilitation

2

Description

Control group: (A sterile water solution and a colored substance similar to that of a solution that has neutral effects) in identical glasses are given in appearance with a droplet

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Adult Hematology and Adult Hematology, Ahvaz , Shafa Hospital

Full name of responsible person

Neda Safikhani

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Sponsors / Funding sources

1

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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

Ahvaz University of Medical Sciences

Proportion provided by this source

50

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

Ahvaz University of Medical Sciences

Full name of responsible person

Nasrin Elahi

Position

Assistant Professor, Faculty of Nursing and Midwifery, Ahwaz Jundishapur University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor. science Committee

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not 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 data found in the related article will be presented.

When the data will become available and for how long

A year after the completion of the research project

To whom data/document is available

Applicants, Students and professors

Under which criteria data/document could be used

Purchased an article from a printed magazine

From where data/document is obtainable

Magazine site

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

Request a purchase, pay the desired amount of the magazine, access to the article

Comments