

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Evaluation of the effect of three compounds (nystatin, aluminum ammonia, and diphenhydramine), mouthwash, chamomile, and mucosamine spray in the treatment of chemotherapy-induced oral mucositis in malignancy in children with leukemia

#### Protocol summary

##### Study aim

Evaluation of the effect of three-component mouthwash (nystatin, aluminum ammonia and diphenhydramine), chamomile and mucosamine spray in the treatment of chemotherapy-induced oral mucositis in pediatric malignancy

##### Design

This study is a double blind clinical trial (statistical specialist and data collector blinding) parallel to phase 3. Two-sided blind and randomized into three groups. The Rand function in Excel software will be used for randomization.

##### Settings and conduct

Pediatric Blood and Oncology Department of Amirkabir Hospital, Arak. Three groups of routine treatment (A), chamomile mouthwash (B) and mucosamine (C), Group A: Routine treatment Group B routine treatment + chamomile Group C: Routine treatment + mucosamine

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Full consciousness, Hospitalized in the oncology ward of Arak Children's Hospital, Similar treatment protocol, Minimum age 2 years and maximum 16 years, Having oral mucosa (minimum score 1), No history of, chamomile mouthwash and mucosamine spray No entry conditions : Dissatisfaction with research, continuous use of painkillers and drugs, gum disease

##### Intervention groups

The three-combination mouthwash is intended as a routine treatment for such children who roll in the morning for 1 minute to 14 days (in all three groups). • In the chamomile group, use chamomile mouthwash for a week, after brushing. Dilute 15 drops of the solution in 10 cc of water, rinse for one minute and do not eat for an hour (B). In the mucosamine group, in addition to prescribing a three-component mouthwash, mucosamine is sprayed 3 times a day on the entire mucous

membrane of the patient's mouth. (Receive daily spray until the 14th day). (Group C) All participants in all three groups receive routine intervention.

##### Main outcome variables

Severity of oral mucositis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210228050519N1**

Registration date: **2021-12-27, 1400/10/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-27, 1400/10/06**

Update count: **0**

##### Registration date

2021-12-27, 1400/10/06

##### Registrant information

##### Name

Khalil Namazi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3505

##### Email address

namazikhalil44@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-21, 1400/09/30

**Expected recruitment end date**

2022-12-21, 1401/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of three compounds (nystatin, aluminum ammonia, and diphenhydramine), mouthwash, chamomile, and mucosamine spray in the treatment of chemotherapy-induced oral mucositis in malignancy in children with leukemia

**Public title**

The effect of three-component mouthwash (nystatin, aluminum MGS and diphenhydramine), chamomile and mucosamine spray in the treatment of oral mucositis caused by chemotherapy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Full consciousness Hospitalized in the oncology ward of Arak Children's Hospital No gum disease Lack of continuous use of painkillers and drugs Similar treatment protocol Minimum age 2 years and maximum 16 years Having oral mucosa (minimum score 1) No history of chamomile mouthwash and mucosamine spray

**Exclusion criteria:**

Improvement of oral mucosa before randomization

**Age**

From **2 years** old to **16 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All children are admitted to the study according to the inclusion criteria and sampling is done in an accessible and easy way. In this study, randomized block method will be used to randomize the three groups of routine treatment (group A), chamomile mouthwash treatment (group B) and mucosamine spray treatment (group C). Children will be divided into three equal groups (A / B / C) using random allocation. In order to perform random allocation, the randomized blocking method with 6 blocks such as AABCC, ABBACC, BBAACC, AACBB, BBCCAA, ACBCAB, etc. will be used, which will have numbers from 1 onwards. Then, by randomly selecting numbers from 1 to n, random sequences of three types of drugs will be identified for the studied samples.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the statistical expert and the evaluator of the outcome are not aware of the type of drug used, so the study is double-blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Payambar aazam (SAW) University Complex, Basij SQ, Sardasht region

**City**

Arak

**Province**

Markazi

**Postal code**

6941-7-38481

**Approval date**

2021-10-17, 1400/07/25

**Ethics committee reference number**

IR.ARAKMU.REC.1400.184

**Health conditions studied****1****Description of health condition studied**

Severity of oral mucositis

**ICD-10 code**

K12.3

**ICD-10 code description**

موکوزیت دهانی

**Primary outcomes****1****Description**

Severity of oral mucositis

**Timepoint**

On the first day (before the intervention), the seventh day and the fourteenth day

**Method of measurement**

Mucosal severity instrument with a scoring range of 0 to 4

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Before starting chemotherapy, all subjects will be taught the correct way to observe oral hygiene, including brushing and flossing. All participants received a three-combination mouthwash (nystatin, aluminum ammojas, and diphenhydramine) as a routine treatment for such children who rolled for 1 minute once a day in the morning (receiving daily mouthwash until the 14th day). After mouthwash, patients do not consume food or fluids for up to 1 hour (group A).

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: • In the chamomile group, use chamomile mouthwash available in pharmacies for a week, three times a day (morning, noon, night) after brushing. Dilute 15 drops of the solution in 10 cc of water and gargle for one minute and do not eat for an hour after that, and the previous standard treatment of the treating physician will continue except for the use of topical mouthwash (group B). (Receive daily mouthwash until the 14th day).

#### Category

Treatment - Drugs

### 3

#### Description

In the mucosamine group (water, sodium, glanzine, propylene glycol, lysine, leucine and proline) in addition to the three-combination mouthwash, mucosamine is sprayed 3 times a day on the entire mucous membrane of the patient's mouth (group C) (spray received) Daily until the 14th day). No drug interactions have been reported for this drug

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirkabir Hospital, Arak

##### Full name of responsible person

Khalil Namazi

##### Street address

Central Province of Arak, Shahid Shiroodi St. Railway, Amirkabir Hospital

##### City

arak

#### Province

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#### Postal code

38196 91187

#### Phone

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#### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

Deputy of research and technology, Payambar aazam (SAW) University Complex, Basij SQ, Sardasht region

##### City

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##### Province

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##### Phone

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##### Email

nnamazikhalil44@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Khalil Namazi

##### Position

Student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Pediatrics

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**Person responsible for scientific inquiries**

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**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Person responsible for updating data**

**Contact**

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**Full name of responsible person**

Khalil namazi

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to  
make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to  
make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to  
make this available