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

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Khalil Namazi

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
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 AABBCC, ABBACC, BBAACC, AACCBB, 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
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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
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Khalil Namazi
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Sponsors / Funding sources

1

Sponsor
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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
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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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