Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Coldamaris Oral Spray in Preventing and Reducing the Severity of Oral Mucositis in Children with Acute Lymphoblastic Leukemia Undergoing Chemotherapy A Randomized Controlled Clinical Trial

Protocol summary

Study aim
To evaluate the effectiveness of Coldamaris oral spray in preventing and reducing the severity of oral mucositis in children with acute lymphoblastic leukemia receiving chemotherapy

Design
Phase 3 randomized controlled clinical trial with two parallel groups and 80 participants, using 1:1 allocation with variable block randomization and blinded outcome assessment

Settings and conduct
The study is conducted at Amir Oncology Hospital, Shiraz. The intervention starts on the first day of induction chemotherapy and continues until the end of induction. The mucositis assessor is blinded to allocation

Participants/Inclusion and exclusion criteria
Children aged 1 to 18 years with newly diagnosed acute lymphoblastic leukemia scheduled for induction chemotherapy; major exclusions are hypersensitivity to Coldamaris, severe active oral lesions, diabetes, primary immunodeficiency, and concurrent malignancy

Intervention groups
The intervention group receives standard oral care plus Coldamaris oral spray, two sprays three times daily. The control group receives standard oral care alone

Main outcome variables
Incidence of severe grade 3 or 4 oral mucositis; maximum mucositis severity during induction chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260815070650N1**
Registration date: **2026-09-20, 1405/06/29**
Registration timing: **prospective**

Last update: **2026-09-20, 1405/06/29**
Update count: **0**

Registration date
2026-09-20, 1405/06/29

Registrant information

Name
Ali Amanati
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2027-09-21, 1406/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Coldamaris Oral Spray in Preventing and Reducing the Severity of Oral Mucositis in Children with Acute Lymphoblastic Leukemia Undergoing Chemotherapy A Randomized Controlled Clinical Trial

Public title

oral Clodamaris in the treatment of chemotherapy-induced mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 1 and 18 years Confirmed diagnosis of acute lymphoblastic leukemia by a pediatric hematologist-oncologist Newly diagnosed acute lymphoblastic leukemia and being scheduled to start induction chemotherapy No previous anticancer treatment before enrollment Decision by the treating physician to initiate standard induction chemotherapy Adequate clinical and performance status to tolerate chemotherapy according to the treating physician Written informed consent provided by a parent or legal guardian Age-appropriate assent provided by children aged 7 years or older

Exclusion criteria:

Known or uncontrolled diabetes mellitus Absolute neutrophil count below 200 cells per microliter at baseline White blood cell count below 1000 cells per microliter at baseline History of severe hypersensitivity or known allergic reaction to Coldamaris or any of its components Presence of an active severe oral lesion at baseline that interferes with mucositis assessment Active severe oral herpes infection at baseline Extensive or multiple aphthous ulcers at baseline Severe or refractory oral candidiasis at baseline Presence of another concurrent malignancy Presence of a primary immunodeficiency disorder Critical clinical condition at baseline that makes oral examination or administration of the intervention impossible

Age

From **1 year** old to **18 months** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be individually allocated to the intervention and control groups using variable block randomization with a 1:1 allocation ratio. The random allocation sequence will be generated by an independent person who is not involved in patient care using statistical software. Variable block sizes will be used to prevent prediction of future treatment assignments. The allocation sequence will be kept in sequentially numbered, opaque, sealed envelopes. After eligibility confirmation and obtaining informed consent, the responsible person will open the corresponding envelope to determine group allocation. Allocation concealment will be maintained until assignment to the study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because no placebo is used, participants, their parents or legal guardians, the principal investigator, and the clinical care team will not be blinded to group allocation. The outcome assessor responsible for evaluating the occurrence and severity of oral mucositis will be blinded to treatment allocation and will not be involved in participant allocation or intervention delivery.

Placebo

Not used

Assignment

Parallel

Other design features

This study is a two-arm, parallel, randomized controlled clinical trial with a 1:1 allocation ratio. Participants will be randomly assigned to either the intervention or control group. The intervention group will receive Coldamaris oral spray in addition to standard oral care, while the control group will receive standard oral care alone. Because no placebo is used, participants, parents, and the clinical care team will be aware of treatment allocation. However, the occurrence and severity of oral mucositis will be evaluated by a trained outcome assessor who is blinded to group allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences, School of Medicine

Street address

Karim Khan Zand Blvd., School of Medicine, Shiraz University of Medical Sciences, Shiraz, Fars, Iran

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2026-08-01, 1405/05/10

Ethics committee reference number

IR.SUMS.MED.REC.1405.185

Health conditions studied

1

Description of health condition studied

Acute Lymphoblastic Leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

2

Description of health condition studied
Oral Mucositis
ICD-10 code
K12.3
ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Incidence of clinically significant oral mucositis of grade 2 or higher
Timepoint
Before the initiation of chemotherapy and on days 3, 7, 10, 14, and 21 after the start of induction chemotherapy, and whenever clinically significant oral symptoms occur
Method of measurement
Assessment and grading of oral mucositis using the World Health Organization Oral Toxicity Scale

2

Description
Incidence of severe oral mucositis of grade 3 or 4
Timepoint
Before the initiation of chemotherapy and on days 3, 7, 10, 14, and 21 after the start of induction chemotherapy, and whenever clinically significant oral symptoms occur
Method of measurement
Assessment and grading of oral mucositis using the World Health Organization Oral Toxicity Scale, the National Cancer Institute Common Terminology Criteria for Adverse Events, and the Western Consortium for Cancer Nursing Research Stomatitis Staging System

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Description: Participants will receive standard oral care in addition to Coldamaris oral spray containing iota carrageenan. The product used will be Coldamaris Rachenspray mit Carragelose, 20 mL, containing 1.2 mg of iota carrageenan, with approximately 0.14 mL delivered per spray. The intervention will start on the first day of induction chemotherapy. Participants will use two sprays three times daily, for a total of six sprays per day, applied locally to the oral mucosa and posterior pharyngeal wall. The spray will preferably be used after meals and after routine oral care. Participants will be advised to avoid eating, drinking, or rinsing the mouth for 20 minutes after administration. The intervention will continue until the end of the induction phase of chemotherapy, approximately four weeks. The product will be supplied by Tachra Pharmed Company.
Category
Prevention

2

Description
Control group: Participants will receive standard oral care according to the hospital protocol. Standard care includes oral hygiene education, mouth rinsing with normal saline or saline plus bicarbonate according to routine ward practice, and supportive care when clinically indicated. Participants in this group will not receive Coldamaris oral spray or any similar preventive topical product. If oral mucositis or other oral complications occur, necessary supportive treatments such as systemic analgesics, topical anesthetics, or nutritional interventions will be provided according to the treating physician's clinical judgment and will be recorded.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Oncology Hospital
Full name of responsible person
Ali Amanati
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Amir Oncology Hospital, Station 11, Farhang Shahr, Shiraz, Fars, Iran
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Web page address
https://amirhosp.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Deputy Director of Research and Technology
Street address
Vice President for Research and Technology, 7th Floor, Shiraz University of Medical Sciences Central Building, Zand Street, Shiraz, Fars, Iran

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https://research.sums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tachra Pharmed

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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ali Amanati
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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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

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified individual participant data, including baseline variables, intervention-related data, oral mucositis assessments, primary and secondary outcomes, and adverse events, together with the study protocol, statistical analysis plan, informed consent form, final study report, and data dictionary, will be available for sharing. All direct identifiers and information that could reasonably permit participant identification will be removed before sharing.

When the data will become available and for how long

Access to the data and study documents will begin six months after publication of the main study results and will remain available for requests for five years following publication of the main results.

To whom data/document is available

Qualified researchers affiliated with universities, research centers, and recognized scientific institutions may request access. Requests from researchers in other organizations may also be considered when they have a clearly defined scientific purpose, meet applicable ethical requirements, and do not present an inappropriate conflict of interest.

Under which criteria data/document could be used

The data and documents may be used only for clearly defined scientific purposes, including secondary analyses, reanalysis of study findings, systematic reviews and meta-analyses, or other relevant scientific research. Applicants must provide a written research objective, research questions, and proposed analysis plan. Commercial use, attempts to reidentify participants, transfer of data to third parties without permission, and use beyond the approved purpose will not be permitted. Ethics approval from the applicant's institution and a data use agreement may be required when applicable.

From where data/document is obtainable

Requests should be submitted to the principal investigator, Dr. Ali Amanati, Shiraz University of Medical Sciences. The official contact information of the principal investigator provided in the clinical trial registry record will be used for correspondence.

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

Applicants must submit a written request including the researcher's identity and institutional affiliation, the purpose of the request, research question, proposed analysis plan, and any required ethics documentation to the principal investigator. The request will be reviewed by the principal investigator and, when necessary, other members of the research team for scientific merit, ethical considerations, confidentiality, and consistency with the informed consent. A decision will normally be communicated within four weeks. Following approval and completion of any required data use agreement, the approved deidentified data or study documents will be provided electronically through a secure method.

Comments

No identifiable participant information will be shared. Data sharing will be subject to the informed consent provisions, ethics committee approval, and applicable regulations of Shiraz University of Medical Sciences.