

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of aloe vera and honey mouthwash on oral mucositis caused by chemotherapy in children with leukemia

#### Protocol summary

##### Study aim

Comparison of the effect of aloe vera and honey mouthwash on oral mucositis caused by chemotherapy in children with leukemia

##### Design

Clinical trials have a control group, with parallel, three-way, blind, randomized phases of phase 3 on 100 children with leukemia under chemotherapy. A random number table has been used for randomization.

##### Settings and conduct

Clinical trials have a control group, with parallel, three-way, blind, randomized phases of phase 3 on 100 children with leukemia under chemotherapy. A random number table has been used for randomization.

##### Participants/Inclusion and exclusion criteria

Children enter the study according to the criteria of entry and exit

##### Intervention groups

Intervention group: first group: mouthwash honey, second group: mouthwash aloe vera, third group: mouthwash combining aloe vera and honey. All three intervention groups, during the first to fourteenth days after chemotherapy, 5 cc of mouthwash, three times daily after meals for 2 minutes in the form of spoons and kept in the mouth so that all parts of the mouth, They use gums and an impregnated tongue. The patient should avoid eating and drinking for up to an hour after rinsing. Control group: Routine section (chlorhexidine mouthwash) and the method of work is according to the intervention group

##### Main outcome variables

During the first, seventh, fourteenth, twenty-first days after chemotherapy, the researcher examined the condition of the mouth based on the ILLERS tool and the condition of the oral cavity using the tools of the World Organization, as well as the pain caused by mucositis. The child who has experienced the most pain during the day will be examined and recorded from 4 groups under study.

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20200222046582N1**

Registration date: **2020-05-20, 1399/02/31**

Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

##### Registration date

2020-05-20, 1399/02/31

##### Registrant information

##### Name

Laya Rabiee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3662 4162

##### Email address

www.rabieel1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison the effect of aloe vera and honey mouthwash on oral mucositis caused by chemotherapy in children with leukemia

**Public title**

The effect of herbal mouthwash on oral mucositis in children with leukemia under chemotherapy

**Purpose**

Prevention

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

Completion of written consent by the child or the child's guardian parent (based on the child's age) for the child's participation in the study Having a child has the necessary ability and cooperation to participate in the study Lack of systemic problems (kidney, liver, etc.) or other malignancies Food allergies or known allergies to aloe vera Lack of diabetes and no history of hyperglycemia The child has oral health before starting chemotherapy (no mucositis) Do not use other mouthwashes during treatment, do not use painkillers continuously, do not use antibiotics

**Exclusion criteria:**

Children undergoing radiotherapy in addition to chemotherapy Children who refuse to continue their studies Patients with neutropenia, fever, gingivitis Teens who smoke and smoke hookah Use of steroidal anti-inflammatory drugs

**Age**

From **6 years** old to **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to the table of random numbers, a random list of numbers one to four will be created using the site [www.randomization.com](http://www.randomization.com) and using SPSS software. When sampling, each patient will be assigned the random numbers in the list, respectively

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In order to blind people, the study of all mouthwashes used in the same and similar containers will be packaged and provided to the research units. The statistical evaluator or analyst is also aware that the samples are marked with code and the analyst is not aware of the allocation of codes to the intervention and control groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study, the concentration / concentration in the detergents is known

**Secondary Ids**

empty

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

Research Ethics Committee of the Faculty of Nursing, Imamate, Mashhad University of Medical Sciences

**Street address**

Shariati 39/17 - No. 24-West Town - Shariati St. - Shariati 39

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9189674496

**Approval date**

2019-12-31, 1398/10/10

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1398.092

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

oral chemotherapy for leukemia in children with leukemia

**ICD-10 code**

C81-C96

**ICD-10 code description**

Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

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

During the first, seventh, fourteenth, twenty-first days after chemotherapy with the help of a researcher examining inflammation of the oral mucosa using the llers tool and the oral cavity condition using the WHO tool, aswell as the pain caused by mucositis (by the child) using the VAS tool And the question of the child who has experienced the most pain during the day? All 4 groups under study will be reviewed and recorded.

**Timepoint**

During the first, seventh, fourteenth and twenty-first days after chemotherapy

**Method of measurement**

With the help of a researcher examining inflammation of the oral mucosa using the ILLERS tool and the oral cavity condition using the WHO mucositis scale tool, as well as pain caused by mucositis (by the child) using the tool and Visual Analogue Scale ask the child which pain is most common during the day. Experienced? All 4 groups under study will be reviewed and recorded

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group is divided into three groups: the first group: honey mouthwash, the second group: aloe vera mouthwash, the third group: mouthwash combining aloe vera and honey). In this study, in the first group: 5% oral mouthwash, The second group: aloe vera mouthwash with a concentration of 50%, the third group: aloe vera mouthwash and honey (aloe vera with a concentration of 25% and honey with a concentration of 2.5%). All three intervention groups, during the first to fourteenth days after chemotherapy, 5 cc of mouthwash, three times daily after meals for 2 minutes in the form of spoons and kept in the mouth so that all parts of the mouth, They use gums and an impregnated tongue. The patient should avoid eating and drinking for up to an hour after rinsing

#### Category

Prevention

### 2

#### Description

In the control group, the routine section (mouthwash with normal saline) will be performed. Children in the control group, during the first to fourteenth days after chemotherapy, 5 cc of mouthwash, three times a day after meals for 2 minutes in the form of pulleys and kept in the mouth so that all parts of the mouth, gums And use the impregnated tongue. The patient should avoid eating and drinking for hours after mouthwash.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hematology-Oncology Department of Dr. Sheikh Mashhad Hospita

##### Full name of responsible person

Zahra Badiie

##### Street address

Mashhad, Tohid Square, Dr. Sheikh Street, Dr. Sheikh Children's Hospita

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

63185- 91399

#### Phone

+98 51 3726 9021

#### Fax

+98 51 3727 7470

#### Email

shaikh.hospital@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghdi

##### Street address

Mashhad: University Street, Central Building of Mashhad University of Medical Sciences

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944-91388

##### Phone

+98 51 3841 2081

##### Fax

+98 51 3841 3006

##### Email

presidentoffice@mums.ac.ir

##### Web page address

<https://relations.mums.ac.ir/website>

#### Grant name

Mashhad University of Medical Sciences Research Vice Chancellor

#### Grant code / Reference number

981031

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

Yes

#### Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Laya Rabiee

**Position**

Nurs

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Postal code**

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**Fax****Email**

www.rabieel1@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Laya Rabiee

**Position**

Nurs

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Laya Rabiee

**Position**

Nurs

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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**

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**

Yes - There is 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**

.The details of the data are not difficult for researchers to present after the end of the project and with the consent of the participants.

**When the data will become available and for how long**

After all the design

**To whom data/document is available**

.The details of the data are not difficult for researchers to present after the end of the project and with the consent of the participants.

**Under which criteria data/document could be used**

After the design and the consent of the participants, the data is available

**From where data/document is obtainable**

It will be announced after the end of the project

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

After the end of the plan

**Comments**

I have no explanation