Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 spools 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 Ilers 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 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 Ilers 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 Ilers tool and the oral cavity condition using the WHO moucositis 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 spools 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 Badiee

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

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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

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Province
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Email
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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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