Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the chamomile and normal saline mouthwash in the prevention of chemotherapy-induced mucositis in children with leukemia

Protocol summary

Study aim
Determination the effect of chamomile and normal saline mouthwash in the prevention of chemotherapy-induced mucositis in children with leukemia

Design
A clinical trial was conducted in two groups of intervention and control with parallel, single-blind, randomized design. Sixty-two subjects were divided into two intervention and control groups.

Settings and conduct
The present study is a single-blind clinical trial in Kermanshah, Iran. Only the participants were unaware and the severity of oral chemotherapy induced by chemotherapy was determined and recorded in eight intervention days in the intervention and control groups, then the severity of the mucositis recorded in the treatment groups was compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: not participated in previous training similar programs in the last three months; having ages 6 to 15 years old; history of acute leukemia; under chemotherapy in the induction or stabilization phase; not having mental, visual or auditory disabilities; no use of immunosuppressive drugs; no underlying illness like kidney disease, gastrointestinal and diabetes; not having oral mucositis before starting treatment. Exclusion criteria: cancel the continued cooperation; not participate in all meetings of intervention; patient died and partially completed questionnaires.

Intervention groups
Intervention group: patients in the intervention group are asked to brush their teeth after each meal and an hour before bedtime, 4 times a day, and 30 drops of chamomile mouthwash (Matrica drops) in half of normal saline Rinse and rinse for 10 seconds, and refrain from eating for 30 minutes, and continue for 16 days. Control group: the same is the intervention group method, but washing is done with normal saline.

Main outcome variables
Chemotherapy oral mucositis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160525028074N2**
Registration date: **2018-05-18, 1397/02/28**
Registration timing: **prospective**

Last update: **2018-05-18, 1397/02/28**
Update count: **0**

Registration date
2018-05-18, 1397/02/28

Registrant information

Name
Nasrin Ghanbari

Name of organization / entity
Tehran University of Social Welfare and Rehabilitation Sciences

Country
Iran (Islamic Republic of)

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+98 21 2218 0083

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nasrin.ghanbari1980@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-10, 1397/03/20

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the chamomile and normal saline mouthwash in the prevention of chemotherapy-induced mucositis in children with leukemia

Public title

Comparison the chamomile and normal saline mouthwash in the prevention of oral mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: not participated in previous training similar programs in the last three months; Having ages 6 to 15 years; History of acute leukemia; Under chemotherapy in the induction or stabilization phase; Not having mental, visual or auditory disabilities; No use of immunosuppressive drugs. Exclusion criteria: Cancel the continued cooperation; Not Participate in all meetings of intervention; patient died and partially completed questionnaires.

Exclusion criteria:

Having underlying illness like kidney disease, gastrointestinal and diabetes Having oral mucositis before starting treatment

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers will be used For randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only participants are unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers will be used For randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Beheshti Blvd, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-04-15, 1397/01/26

Ethics committee reference number

IR.KUMS.REC.1397.107

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

Z85.8

ICD-10 code description

Personal history of malignant neoplasms of other organs and systems

Primary outcomes

1

Description

Oral Mucositis

Timepoint

Before and 16 days after starting chemotherapy

Method of measurement

WHO Scale for Mucositis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients in the intervention group are asked to brush their teeth after each meal and an hour before bedtime, 4 times a day, and 30 drops of chamomile mouthwash (Matrica drops) in half of the normal saline cans to be washed. Gargle for 10 seconds, and refrain from eating for 30 minutes, and continue for 16 days.

Category

Prevention

2

Description
Control group: For the control group, only routine interventions were performed.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Mohammad Kermanshahi Children 'hospital
Full name of responsible person
Nasrin Ghanbari
Street address
Helal Ahmar crossroads, Dr Mohammad Kermanshahi Children 'hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
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Nasrin Ghanbari
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammad Reza Golpaigani
Position
Associate professor
Latest degree
Subspecialist
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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
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