Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of effect of topical utilization of Honey and Chamomile for Prevention on Chemotherapy-induced Mucositis in Children with Leukemia

Protocol summary

Summary

The aim of the study was to compare the effectiveness of topical application of Honey and Chamomile in the prevention of Chemotherapy-induced Mucositis in children with Leukemia. The study is a single blind clinical trial. Inclusion criteria: Children 1 to 14 years old with Leukemia who were admitted for Chemotherapy in Imam Ali Hospital, Zahedan, Iran. Exclusion criteria: Children who have undergone Surgery and Radiotherapy in addition to Chemotherapy and Children who also have Systemic Leukemia or other malignancies. The study will include 40 children 1 to 14 years of age during 2014. The severity of Mucositis will be measured according to WHO standard tables with observations by a probe and mirror under headlight.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409133549N7**
Registration date: **2014-10-20, 1393/07/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-20, 1393/07/28

Registrant information

Name

Foroogh Amirabadi

Name of organization / entity

Dental College, Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

amirabadi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice -Chancellery for Research, Zahedan University of Medical Sciences

Expected recruitment start date

2014-05-20, 1393/02/30

Expected recruitment end date

2014-08-01, 1393/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of topical utilization of Honey and Chamomile for Prevention on Chemotherapy-induced Mucositis in Children with Leukemia

Public title

Impact of mouthwashes on Mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children 1 to 14 years old with Leukemia who were admitted for Chemotherapy in the Zahedan Imam Ali Hospital. Exclusion criteria: Children who underwent Radiotherapy and Surgery in addition to Chemotherapy and Children who also have Systemic Leukemia or other Cancers.

Age

From **1 year** old to **14 years** old

Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Single blind means that researcher is not aware from type of mouthwash which is given to each patient. Each patient who comes to the study is selected by the nurse of the department and is allocated to one of the groups (interventions, positive or negative controls). Mouthwash is administered to them while the researcher is not aware from the type of mouthwash.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences.
Street address
Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran
City
Zahedan
Postal code
۹۸۱۶۷۴۳۴۶۳
Approval date
2014-05-17, 1393/02/27
Ethics committee reference number
6257/ 12 /م

Health conditions studied

1

Description of health condition studied
Mucositis induced by Chemotherapy in children with Leukemia
ICD-10 code
L55-L59
ICD-10 code description
بیماریهای پوستی و مخاطی ناشی از رادیوتراپی

Primary outcomes

1

Description
Mucositis
Timepoint
On the first day, Seventh and fourteenth day after starting Chemotherapy
Method of measurement
Based on observation by probe and mirror under headlight

Secondary outcomes

empty

Intervention groups

1

Description
Honey diluted to a concentration of 12/5%, every two hours during waking hours for 14 days
Category
Prevention

2

Description
Chamomile Mouthwash , Baryj Essence, Kerman, Iran, every two hours during waking hours for 14 days
Category
Prevention

3

Description
Positive control, Chlorhexidine, ShahrDaruo, Tehran, Iran, every two hours during waking hours for 14 days
Category
Prevention

4

Description
Negative control, Normal saline, Samen, Mashhad, Iran, every two hours during waking hours for 14 days
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan Imam Ali Hospital
Full name of responsible person
Doctor Amirabadi Foroogh

Street address
Imam Ali Hospital, Doctor Hesabi Sq. Persian Gulf Highway, Zahedan, Iran
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice - Chancellery for Research, Zahedan University of Medical sciences
Full name of responsible person
Doctor Mahmoodzade Sagheb Hamid Reza
Street address
Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran
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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
Vice - Chancellery for Research, Zahedan University of Medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Dental College of Zahedan University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty