Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparing the impact of using olive and coconut oils in preventing of chemotherapy induced mucositis in children with leukemia

Protocol summary

Study aim
Determining the severity of mucositis in children undergoing chemotherapy after exposure to olive and coconut oil in a certain period.

Design
Clinical trial, double-blind, randomized, on 100 patients

Settings and conduct
In each group of patients referred to Imam Ali Zahedan Hospital, a sterile sponge dipped in the desired substance every two hours during waking hours and from the first day of chemotherapy for 14 days to the palate, cheek and surface the back and belly of the tongue will be rubbed by a trained nurse. For each use, a new sponge will be dipped in one of the ingredients and 5 ml will be applied to the tongue, buccal mucosa, lips and dorsal and ventral surfaces of the tongue and hard palate. Then, the condition of the patients will be examined in terms of the degree of mucositis in the time intervals announced by a pediatric dental resident.

Participants/Inclusion and exclusion criteria
Children aged 1 to 14 years who have healthy oral mucosa and do not have any systemic diseases and allergies to olive and coconut oil. All interventions are subject to the informed consent of patients and parents. If any of the inclusion criteria are not met, the patient will be excluded from the study.

Intervention groups
Olive oil group: used to prevent mucositis. Coconut oil group: It is used to prevent mucositis. Chlorhexidine mouthwash group: used as a positive control group. Normal saline mouthwash group: used as a negative control group.

Main outcome variables
Reduction of pain resulting from chemotherapy-induced oral cavity. Enhancing child nutrition during chemotherapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240126060812N1**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date
2024-02-19, 1402/11/30

Registrant information

Name
Mahsa Moradi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3345 0105

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the impact of using olive and coconut oils in preventing of chemotherapy induced mucositis in children with leukemia

Public title
Copmparsion the effect of olive oil and coconut in preventing mucosities induced by chemotherapy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children 1-14 years old Not receiving any type of treatment in the past Healthy mucosa at the beginning of treatment By obtaining the informed consent of the patient and the patient's parents Children who have not undergone radiotherapy and surgery in addition to chemotherapy.
Exclusion criteria:
Children who have undergone chemotherapy, radiotherapy, and surgery Children who, in addition to leukemia, also suffer from other systemic or malignant disorders Children who have received any anti-fungal or anti-viral drug or any substance that is effective on oral mucositis before entering the study.
Age
From **1 year** old to **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, block In order to randomly select patients using the block randomization method, with a total sample size of 13, we will have 8 blocks of size 8. After the first patient visits, one of these blocks will be randomly selected, and the patient will be assigned to the corresponding group based on that block.
Blinding (investigator's opinion)
Double blinded
Blinding description
Sampling is random and purpose-based, and the double-blind study is easy and accessible. Allocation method of blocks of 8 will be used according to the total number of samples. In order to randomly select patients using the block randomization method, with a total sample size of 13, we will have 8 blocks of size 8. After the first patient visits, one of these blocks will be randomly selected, and the patient will be assigned to the corresponding group based on that block.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Pedodontics Department,School of Dentistry.,Azadegan Blvd.
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Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Approval date
2023-12-24, 1402/10/03
Ethics committee reference number
IR.ZAUMS.REC.1402.397

Health conditions studied

1

Description of health condition studied
Leukemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description
Prevention of mucusitis
Timepoint
In the first days, the first week, and the fourth week after the intervention
Method of measurement
Assessed based on the classification of the World Health Organization and clinical examination of the mucosal status

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, olive oil (Farabakr Company, Rudbar, Iran), which is stored in dark glass containers at room temperature, is used to prevent mucositis.
Category
Prevention

2

Description
Intervention group:In this group, coconut oil (DR-GEORGE, Germany) stored in metal cans at room temperature is used to prevent mucositis.
Category
Prevention

3

Description
Control group:In this group, chlorhexidine mouthwash (0.2% chlorhexidine mouthwash, Najo, Iran) is used as a positive control group to prevent mucositis.
Category
Prevention

4

Description
Control group:In this group, normal saline mouthwash (Darupakhsh, Iran) is used as a negative control group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Hospital in Zahedan
Full name of responsible person
Mahsa Moradi
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Sponsors / Funding sources

1

Sponsor
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Grant name
Department of research and information technology
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Dr Mahsa Moradi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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
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
Information regarding the primary outcomes and group comparisons will be published two months after the study concludes
When the data will become available and for how long
Two months after the study's completion
To whom data/document is available
Dental students and researchers
Under which criteria data/document could be used
will be provided with information about the mucositis developed following chemotherapy treatment
From where data/document is obtainable
dr.mahsamoradi.pediatric@gmail.com Dr.mahsa moradi
What processes are involved for a request to access data/document
by sending an email to the email address of the responsible person for the research project
Comments