

# 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)

##### Phone

+98 54 3345 0105

##### Email address

dr.mahsamoradi.pediatric@gmail.com

##### 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.

##### City

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 mucositis

#### 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

#### Street address

Pedodontics Department, School of Dentistry., Azadegan Blvd.

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dr.mahsamoradi.pediatric@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Dr Ebrahim Kord

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#### Email

zaums.research@zaums.ac.ir

### 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

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences

**Full name of responsible person**  
Forough Amirabadi

**Position**  
Associate professor

**Latest degree**  
Specialist

**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