

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The comparison of the effect of chlorhexidine and combination of chlorhexidine-persica mouthwashes on chemotherapy-induced mucositis of children with hematologic malignancies

#### Protocol summary

##### Summary

The purpose of this study is to compare the effect of chlorhexidine mouthwash with combination of chlorhexidine-persica mouthwash on chemotherapy-induced mucositis of children with hematological malignancies. Six to 12 year old children with hematological malignancy who are under a similar treatment protocol will be enrolled in the study. Children who demonstrate infection or sensitivity following the administration of any of the mouth-rinses will be excluded. Accordingly, 40 patients selected will be randomly assigned to one of two experimental groups after obtaining the appropriate informed consent. Randomization will be performed using the [www.randomizer.org](http://www.randomizer.org) website. Oral hygiene cares will be instructed by the clinician to all of the patients and their parents. The incidence and severity of the mucositis will be evaluated by using a questionnaire designed based on the World Health Organization (WHO) index for incidence and severity of mucositis and Oral Assessment Guide (OAG) index for severity of mucositis. Then, the patients will be instructed to rinse either with normal saline (15 ml) or persica oral drops (10 drops in 15 ml water), based on their corresponding group, twice a day for two weeks. Subsequently, patients in both groups will rinse with 15 ml of chlorhexidine for 30 seconds and avoid eating for an hour. A second oral examination will be performed on the 8th and 15th day using the same questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060117935N1**

Registration date: **2014-07-15, 1393/04/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-15, 1393/04/24

##### Registrant information

###### Name

Zahra Bahrololoomi

###### Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1624 0691

###### Email address

zbahrololoom@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shahid Sadoughi University of Medical Sciences of Yazd

##### Expected recruitment start date

2014-06-10, 1393/03/20

##### Expected recruitment end date

2014-08-11, 1393/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of the effect of chlorhexidine and combination of chlorhexidine-persica mouthwashes on chemotherapy-induced mucositis of children with hematologic malignancies

##### Public title

Evaluating the effect of simultaneous use of persica and chlorhexidine on chemotherapy-induced oral ulcers of children between 6 and 12 year old

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: age range of 6-12 years; history of hematologic malignancies with the same treatment protocol; no history of sensitivity to any substances; no history of asthma, allergic rhinitis and dermatitis; no need of radiotherapy; written informed consent obtained from parents or legal guardian. Exclusion criteria: occurrence of any infection; occurrence of sensitivity to mouth-rinses.

### **Age**

From **6 years** old to **12 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences

##### **Street address**

Central Organization for Shahid Sadoughi University of Medical Sciences, Bahonar Sq., Yazd

##### **City**

Yazd

##### **Postal code**

8916978477

#### **Approval date**

2014-05-03, 1393/02/13

#### **Ethics committee reference number**

17/1/31866/پ

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Chemotherapy-induced mucositis

#### **ICD-10 code**

K13.7

#### **ICD-10 code description**

Other and unspecified lesions of oral mucosa

## **Primary outcomes**

### 1

#### **Description**

Incidence of mucositis

#### **Timepoint**

Day 1 (before intervention), 8 and 15

#### **Method of measurement**

World Health Organization (WHO) grading

### 2

#### **Description**

Severity of mucositis

#### **Timepoint**

Day 1 (before intervention), 8 and 15

#### **Method of measurement**

World Health Organization (WHO) grading; Oral Assessment Guide (OAG) grading

## **Secondary outcomes**

### 1

#### **Description**

Severity of pain

#### **Timepoint**

Day 1 (before intervention), 8 and 15

#### **Method of measurement**

Facial Image Scale

## **Intervention groups**

### 1

#### **Description**

Rinsing with normal saline (15 ml) followed by chlorhexidine 0.2% mouthwash (15 ml), 2 times a day (after breakfast and dinner) for 2 weeks

#### **Category**

Prevention

### 2

#### **Description**

Rinsing with persica oral drops (10 drops in 15 ml water) followed by chlorhexidine 0.2% mouthwash (15 ml), twice a day (after breakfast and dinner) for 2 weeks

#### **Category**

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Private Clinic of Dr. Azam Sadat Hashemi

**Full name of responsible person**

Dr. Azam Sadat Hashemi

**Street address**

Atlasi Building, Atlasi Sq.

**City**

Yazd

2

### Recruitment center

**Name of recruitment center**

Shahid Sadoughi Hospital of Yazd

**Full name of responsible person**

Dr. Azam Sadat Hashemi

**Street address**

Ebne Sina Ave.

**City**

Yazd

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research of Shahid Sadoughi University of Medical Sciences of Yazd

**Full name of responsible person**

Dr. Fateme Ezoddini Ardakani

**Street address**

Shahid Sadoughi University of Medical Sciences, Bahonar Sq., Yazd

**City**

Yazd

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research of Shahid Sadoughi University of Medical Sciences of Yazd

**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

**Name of organization / entity**

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

**Full name of responsible person**

Dr. Yasamin Khaksar

**Position**

Postgraduate student of pediatric dentistry

**Other areas of specialty/work**

**Street address**

Faculty of Dentistry, Dahe Fajr Blvd., Yazd

**City**

Yazd

**Postal code**

**Phone**

+98 35 1625 5881

**Fax**

**Email**

yasamin.khaksar@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr. Azam Sadat Hashemi

**Position**

Hematology Oncology and Genetics Research Center, Shahid Sadoughi University of Medical Sciences

**Other areas of specialty/work**

**Street address**

Department of Pediatrics, Hematology, Oncology and Genetics Research Center, Shahid Sadoughi University of Medical Sciences, Yazd

**City**

Yazd

**Postal code**

**Phone**

+98 35 1822 9104

**Fax**

**Email**

drazamhashemi@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Dental Faculty of Shahid Sadoughi University of Medical Sciences-Yazd

**Full name of responsible person**

Dr. Yasamin Khaksar

**Position**

Postgraduate student of pediatric dentistry

**Other areas of specialty/work**

**Street address**

Faculty of Dentistry, Dahe fajr Blvd., Yazd

**City**  
**Postal code**  
**Phone**  
+98 35 1625 5881  
**Fax**  
**Email**  
yasamin.khaksar@gmail.com  
**Web page address**

## 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*