Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of the effect of chlorhexidine and combination of cholorhexidine-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 cholorhexidine-persica mouthwash on chemotherapy-induced mucositis of children with hematomalignancies. Six to 12 year old children with hematomalignancy 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 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

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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 cholorhexidine-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 Sadoghi 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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Hematology Oncology and Genetics Research Center, Shahid Sadoughi University of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

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Position
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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