Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison between topical mouth rinse and chamomile mouthwash on chemotherapy-induced mucositis in children with cancer referred to 17 shahrivar hospital in Rasht.

Protocol summary

Summary

The purpose of this study is to compare between topical mouth rinse and chamomile mouthwash on chemotherapy-induced mucositis in children with cancer. 6 to 15 years old children with cancer 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, after obtaining the appropriate information consent Patient selected will be approach to goal and then randomly divided into two groups based on the clinical trial. Randomization will be performed using nurses. Oral hygiene cares will be instructed by the clinical to all or the patients and their parents. The incidence and severity of the mucositis will be evaluated by using a questionnaire designed based on mucositis WHO Checklist. Oral examination will be performed on the Before intervention and 7th and 14th day using the same questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040821658N1**
Registration date: **2016-03-08, 1394/12/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-08, 1394/12/18

Registrant information

Name
Fatemeh Pourdeghatkar
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Islamic Azad University
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between topical mouth rinse and chamomile mouthwash on chemotherapy-induced mucositis in children with cancer referred to 17 shahrivar hospital in Rasht.

Public title

The comparison of the effect topical mouth rinse and chamomile mouthwash on chemotherapy-induced mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: not having tooth and gum diseases, avoiding the use of persistent analgesics and opioid, a similar treatment protocol minimum age 6 years and

maximum age 15 years Exclusion criteria: non cooperation, the incidence of allergy to mouthwash or solution, Stomatitis and mucositis incidence before chemotherapy.

Age
From **6 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University of Isfahan(Khorasgan)

Street address
University Blvd , Arghavanieh , Jay Street East, Isfahan

City
Isfahan

Postal code
81595-158 post box

Approval date
2015-07-05, 1394/04/14

Ethics committee reference number
number 3331-5-14-04-94 ، code IR.MUI.REC.1394.4.38

Health conditions studied

1

Description of health condition studied
Mucositis

ICD-10 code
K13

ICD-10 code description
Other diseases of lip and oral mucosa

2

Description of health condition studied
Acute lymphoblastic leukemia

ICD-10 code
C91.0

ICD-10 code description
Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description
Mucositis

Timepoint
A day before chemotherapy, seventh day, the fourteenth day

Method of measurement
Check List of Oral Mucositis Assessment of the World Health Organization

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group for rinsing with mouthwash position according to the doctor, the nurse pills powder first and then with sodium bicarbonate and normal saline composition becomes half the patients are given a day before chemotherapy for a week, every day after brushing three times a day (morning, afternoon, evening) and every 10 cc without diluting gargle for a minute and they will not eat up an hour later than the previous standard treatment doctor Apart from the use chamomile will continue treating

Category
Prevention

2

Description
Patients in the control group to wash the mouth of chamomile mouthwash in pharmacies(drops 30 ml mouthwash Matrica making Barij Essence Kashan)from the day before chemotherapy for a week, every day after brushing three times a day (morning, noon night) use. so that 15 drops of the solution diluted in 10 ml of water and gargle for a minute and they will not eat up an hour later And previous standard treatment, your doctor will continue with the exception of local mouthwash.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Hospital in Rasht
Full name of responsible person
Fatemeh pourdeghatkar
Street address
17 shahrivar Hospital in Rasht, Namjoo Street, City of Rasht, Guilan province
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Fatemehpourdeghatkar
Street address
Namjoo Street Hospital shahrivar 17
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
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
17 Shahrivar Hospital in Rasht
Full name of responsible person
Fatemeh pourdeghatkar
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Person responsible for updating data

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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