

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 2474

Email address

f.pourdeghatkar@khuif.ac.ir

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

Position

BSc in Nursing

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty