

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The comparison of Effectiveness of mouthwash Benzydamine and combination of Benzydamine-Sucralfate in patients with malignancy undergoing chemotherapy

Protocol summary

Summary

The purpose of this study is the comparison of effectiveness of mouthwash Benzydamine and combination of Benzydamine-Sucralfate in patients with malignancy undergoing chemotherapy. The patients with leukemia [acute lymphoid leukemia (ALL) or acute myeloid leukemia (AML)], new cases at the start of chemotherapy are targeted population. Twenty four patients (twelve patients in each group: six with AML and six with ALL) constitute the sample size. At the beginning of chemotherapy with coordination of the oncologist the patient is placed in one of two groups, group X (benzydamine) or Y (benzydamine-sucralfate) by nurse (of research team). At first day, the researcher educates oral hygiene to the patients and then records the condition of their mouth's health with a questionnaire based on the targeted group, then the nurse gives medication and educates the directions of usage to group X and Y. On the days of 6, 9, 12, and 14 the patients' mouth will be examined and also the condition of the mouth will be recorded based on the questionnaire and at the end, statistical analysis will be done. Possess one of hematologic malignancies(ALL or AML) according to the oncologist- similar chemotherapy treatment planning- patients who are at beginning of their chemotherapy courses (new case) and absence of any fungal ,viral or other lesions in the patient's mouth are inclusion criteria. Appearance of fungal or viral lesions in the patient's mouth or lack of patient cooperation at protocol X or Y are among exclusion criteria. Mouthwash Benzydamine and combination of Benzydamine-Sucralfate are interventions of the research. Pain, erythema , ulcer and stomatitis are primary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101311099N1**

Registration date: **2013-05-18, 1392/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-18, 1392/02/28

Registrant information

Name

Mahrooz Ershadi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd

Country

Iran (Islamic Republic of)

Phone

+98 937 326 4731

Email address

drershadi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Sadoghi University of Medical Sciences- Yazd

Expected recruitment start date

2012-09-11, 1391/06/21

Expected recruitment end date

2013-04-10, 1392/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Effectiveness of mouthwash Benzylamine and combination of Benzylamine-Sucralfate in patients with malignancy undergoing chemotherapy

Public title

Prevention of chemotherapy-induced stomatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Possess one of hematologic malignancies(acute lymphoid leukemia (ALL) or acute myeloid leukemia (AML) according to the oncologist-similar chemotherapy treatment planning- patients are beginning to chemotherapy (new case)- absence of any fungal,viral or other lesions in the patient's mouth
Exclusion criteria: appearance of fungal or viral lesions in the patient's mouth- lack of patient cooperation protocol X or Y

Age

From **14 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The study is double-blind because: The labels of medications are peeled so the patient is not aware of the type of drug. The examiner does not give the drugs to the patients, but also the advisor of project gives the drugs and educates application of it to the patient. He does not have any role in the examination. Method of randomization: Using software to Random Number Generation patients are randomly assigned to one of two groups: X or Y.

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

2012-09-11, 1391/06/21

Ethics committee reference number

83152/1/17/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**

Pain

Timepoint

Day 0(Concurrent with intervention)-days 6,9,12 and 14 after the start of intervention

Method of measurement

VAS scale

2**Description**

Erythema

Timepoint

Day 0(Concurrent with intervention)-days 6,9,12 and 14 after the start of intervention

Method of measurement

Square centimeter

3**Description**

Grading of stomatitis

Timepoint

Day 0(Concurrent with intervention)-days 6,9,12 and 14 after the start of intervention

Method of measurement

WHO grading

4**Description**

Ulcer

Timepoint

Day 0(Concurrent with intervention)-days 6,9,12and 14

after the start of intervention
Method of measurement
Square centimeter

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Mouthwash Benzydamine hydrochloride .15%, produced by Behvazan company-three times a day- after meal 15 ml- rinse and spit out

Category

Prevention

2

Description

Intervention group: Combination of Benzydamine-Sucralfate (mouthwash Benzydamine hydrochloride .15%15ml + powdered tab sucralfate 500 mg)-three times a day after meal -rinse and spit out sucralfate powder is produced of sucralfate tablets (500 mg) of Soha company

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Mohammad Forat Yazdi

Street address

Shahid Dashti Blvd.Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Sadoghi University of Medical Sciences- 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 Sadoghi University of Medical Sciences- 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

Department of Oral Medicine Faculty of Dentistry
Shahid Sadoghi University of Medical Sciences-Yazd

Full name of responsible person

Dr.Mahrooz Ershadi

Position

Resident(postgraduate student)

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Specialist

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Person responsible for updating data

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Full name of responsible person

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Postgraduate student of oral medicine

Other areas of specialty/work

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Fax

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