Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effect of mouthwashes containing tranexamic acid and nanotransexamic acid for controlSpontaneous intraoral bleeding in leukemia patients: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of mouthwashes containing tranexamic acid and nanotransexamic acid to control spontaneous intraoral bleeding in leukemia patients referred to the dental clinic of Golestan University of Medical Sciences in 1402

Design

Clinical trial with control group, parallel groups, single blind, randomized, phase 3 on 52 patients, Excel software was used for randomization.

Settings and conduct

In this single-blind clinical trial study, the participants were 52 leukemia patients who referred to the oncology unit of the Deziani Clinic of Golestan University of Medical Sciences in 1402, by examining the entry and exit criteria and obtaining informed consent based on the university's code of ethics. will be selected. Patients are randomly assigned to two groups of mouthwash containing tranexamic acid and nanotransamic acid. Patients will be compared pre and post with themselves as well as with other drug group. At first, the patient is asked about the number of oral bleeding times during the day. Then the number of oral bleeding areas is checked by the examiner.Finally, the presence or absence of oral bleeding after using mouthwash will be investigated.

Participants/Inclusion and exclusion criteria

Conditions for entering the study 1-Patients diagnosed with thrombocytopenia 2-Leukemia patients with oral bleeding 3-Similar bleeding frequency 4-Same time interval from chemotherapy Conditions for withdrawal from the study 1-allergy 2-Pregnant or lactating mother 3-smoking 4-periodontitis 5-Prohibition of anticoagulants 6-Contraceptive pills 7-Use of anticoagulants

Intervention groups

The control group was given mouthwash containing tranexamic acid and the case group was given mouthwash containing nanotransamic acid.

Main outcome variables

Bleeding frequency; presence of bleeding; number of bleeding interdental areas

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230104057046N2**
Registration date: **2023-03-12, 1401/12/21**
Registration timing: **prospective**

Last update: **2023-03-12, 1401/12/21**
Update count: **0**

Registration date

2023-03-12, 1401/12/21

Registrant information

Name

Nazanin Mortazavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 5671

Email address

dr.mortazavi@webmail.goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-16, 1401/12/25

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of mouthwashes containing tranexamic acid and nanotransexamic acid for controlSpontaneous intraoral bleeding in leukemia patients: A randomized clinical trial

Public title

A comparative study of the effect of mouthwashes containing tranexamic acid and nanotrangasemic acid in leukemia patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Leukemia patients with oral bleeding Patients diagnosed with thrombocytopenia (platelet count less than 20,000 units) Selection of patients with the same frequency of use as assigned random classification Selection of patients with the same interval of chemotherapy

Exclusion criteria:

Use of any anti-coagulant or anti-coagulant drugs (such as ASA, NSAID, ...) in the last month Pregnant or nursing mothers Hypersensitivity to tranexamic acid Use of birth control pills Smokers Presence of severe periodontitis The presence of diseases that prohibit the use of anticoagulants

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

We select patients from those who refer to the Desiani clinic of Golestan University of Medical Sciences according to the study entry and exit criteria. Then, based on the severity of the disease, we divide them into two groups, moderate and weak, and enter the names in a double list (in the form of a and b) in the Excel software. Then, the names are sorted separately based on random numbers for each list, and assigned to each of the drug groups one by one.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are unaware of the allocation of study groups. Bottles containing medicine are the same for both control and intervention groups. The intervention and control groups are divided into A and B, and the test participants have no knowledge of the type and group to be tested.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Philosophical Higher Education Complex، the beginning of the Sixty Hats Road، Gorgan

City

Gorgan

Province

Golestan

Postal code

49341-74515

Approval date

2023-01-17, 1401/10/27

Ethics committee reference number

IR.GOUMS.REC.1401.556

Health conditions studied

1

Description of health condition studied

Spontaneous oral bleeding in leukemia patients

ICD-10 code

C95

ICD-10 code description

Leukemia of unspecified cell type

Primary outcomes

1

Description

The number of times of spontaneous oral bleeding؛ the presence of spontaneous oral bleeding؛ the number of bleeding interdental areas after using an interdental toothbrush by the researcher

Timepoint

Measuring the number of bleeding interdental areas before the start of the intervention and 14 days after the start of the intervention؛ Measuring the number of bleeding times before and after using mouthwash (every day up to two weeks)؛ Identifying the presence of oral bleeding before and after using mouthwash (every day up to two weeks)

Method of measurement
Evaluation of the presence of bleeding by questionnaire - Evaluation of the number of bleeding areas by the researcher through interdental toothbrushes - Evaluation of the number of bleeding times by questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group The intervention group receives five percent nanotrangasmic acid mouthwash. Each subject will receive 4 containers of 280 ml containing mouthwash. Each patient is taught to use 20 ml mouthwash four times a day for 14 days. The participant is allowed to eat half an hour after using the mouthwash. The mouthwashes are made by pharmacists and experts in the nano field who are present as consultants in the project.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Deziani Hospital of Medical Sciences
Full name of responsible person
Dawood Mozaffari
Street address
Collection of higher philosophical education, The beginning of the Sixty Hats Road
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Golestan
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4934174515
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges Begum Mirbehbani
Street address
Dental Research Center، Gorgan Dental College، Shahreer five، Shahryar townl
City
Gorgan
Province
Golestan
Postal code
4913983635
Phone
+98 17 3262 8052
Email
aliyesensebli@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Aliye sensebli
Position
Dentistry student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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aliyesensebli@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Nazanin Mortazavi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Aliye sensebli

Position

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Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Potential data can be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts six months after the publication of the results

To whom data/document is available

Researchers working in academic and scientific institutions in the country can access the data and other documents of this study with a written request from (Gorgan Dental School Research Center).

Under which criteria data/document could be used

The documents will be made available to the applicants after obtaining permission from the project promoters and the research director of Golestan University of Medical Sciences and with a written request from (Research Center of Gorgan Dental School). Obviously, it takes time during the administrative procedures, and we try to do it within a month from the date of the request.

From where data/document is obtainable

Gorgan, Shahrek Shahryar, 5 Shahryar, Gorgan Dental College, Dental Research Center, Mrs. Shabani, Research Center Expert, Postal Code 4913983635, Phone Number 28853262017, Email s.shabani8791@gmail.com

What processes are involved for a request to access data/document

Researchers working in academic and scientific institutions in the country can access the data and other documents of this study by making a written request from (Gorgan Dental Faculty Implementation Center). The documents will be available to the applicants after obtaining the permission from the project managers and the research director of Golestan University of Medical Sciences. Obviously, the administrative procedures take time and we try to do it within a month from the date of the request.

Comments