Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of the efficacy of topical tranexamic acid in the control of acute epistaxis

Protocol summary

Study aim

This study aims to evaluate the effect of the local use of tranexamic acid in the control of epistaxis.

Design

It was randomized, placebo-controlled, with parallel groups, triple-blind, phase 2-3 trial on 106 patients. The randomization website was used for randomization.

Settings and conduct

In this study, patients who come to the ER of two tertiary hospitals are selected. The initial diagnosis of epistaxis is performed by an emergency medicine specialist, and after obtaining informed consent, the eligible patients are randomly assigned to the drug or placebo group. To blind the care providers and participants, both solutions are prepared with the same shape and color, and they are not aware of the contents of the prescribed solution. With the control of epistaxis, they discharged with nasal sprays.

Participants/Inclusion and exclusion criteria

The participants in this study are patients over 18 years old who have spontaneous nosebleeds (not following trauma) and do not have underlying diseases (e.g. sinonasal or nasopharynx malignancy). Those who do not agree to enroll or are considered high-risk groups in terms of drug prescription will be excluded from the study.

Intervention groups

In the interventional group, participants were discharged with tranexamic acid nasal spray after ceasing epistaxis with primary conservative management for 3 days. The first dose is sprayed in the emergency room. Patients in the control group are discharged after nosebleeds cease due to primary treatments with sodium chloride 0.9% prepared as a nasal spray. It is prescribed as the same as the interventional group.

Main outcome variables

The primary outcome is the number of patients with control of bleeding within 7 days in each group. The essential secondary outcomes are the time to stop bleeding after intervention, the rate of rebleeding within 24 hours, and the rate of adverse events within 7 days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221230056992N1**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

seyed ermia mousavi mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 4082

Email address

ermiamsm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-12-05, 1403/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of topical tranexamic acid in the control of acute epistaxis

Public title
Effect of topical tranexamic acid in the treatment of epistaxis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with acute spontaneous epistaxis age more than 18 epistaxis is controlled with primary conservative management patient has a consent to enroll the study

Exclusion criteria:
sensitivity to tranexamic acid no consent to enroll the study there is any malignancy in the nasopharynx, nasal cavity or sinonasal tract prior packing in nasal cavities when come to ER pregnancy or breastfeeding history of coagulopathies hemodynamic instability second stage of hypertension (SBP>=160 and DBP>=100) epistaxis following trauma history of recent myocardial infarction or stroke renal dysfunction history of thromboembolism or seizure

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
It is prepared for the random assignment of random numbers with the help of 'randomization.com'. The opaque closed envelope method is used for random concealment. In this method, randomly assigned numbers are written in order and placed inside the envelope. The contents of the envelope will not be visible from the outside. For each patient, after entering the study and obtaining consent, an envelope is opened, and based on the envelope's contents, the individual is placed in the intervention or control group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants and care providers are blind due to the drug and placebo provide in the same color and matter, it is presented to them with "A" or "B" stickers. Data are also given to data analyser in the two forms of "A" or "B".

Placebo
Used

Assignment
Parallel

Other design features
There is no study assessing the effect of tranexamic acid nasal spray in the control of epistaxis in Iran, yet.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Faculty of Medicine of Mashhad University of Medical Sciences

Street address
East door of University Campus, Azadi square, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2023-05-02, 1402/02/12

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.081

Health conditions studied

1

Description of health condition studied
Haemorrhage from nose, Nosebleed

ICD-10 code
R04.0

ICD-10 code description
Epistaxis

Primary outcomes

1

Description
Number of patients without recurrent epistaxis during 7 days

Timepoint
first day, days 3 and 7 after intervention

Method of measurement
participants statement

Secondary outcomes

1

Description

Time to control bleeding

Timepoint

minutes to hours after intervention

Method of measurement

physical examination

2

Description

occurrence of side effects during 7 days

Timepoint

7 days after intervention

Method of measurement

patient statement

Intervention groups

1

Description

Intervention group: Tranexamic acid ampule (100 mg/ml) is prepared as a nasal spray and its volume is 5cc given 5 puffs every 12 hours for 3 days.

Category

Treatment - Drugs

2

Description

Control group: Sodium chloride (0.9 percent) was prepared as a nasal spray with a volume of 5cc, prescribed 5 puffs every 12 hours for 3 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Ermia Mousavi

Street address

Emamreza Hospital Square, Ibn Sina Ave, Mashhad

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2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafagodi

Street address

Ghoreishi Building, Close to Howveizeh Cinema, Daneshgah Ave, Mashhad

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohamadreza Majidi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Ahmad Abad Ave, Ghaem Hospital, Mashhad

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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
Title: "Data of participants in effects of TA on Epistaxis control study" All collected deidentified data (IPD) are accessible.

When the data will become available and for how long
Documents will be accessible one year after publishing.

To whom data/document is available
this is only available for people working in academic institutions.

Under which criteria data/document could be used
It will only be presented for familiarization with the data collection process, and analysis of the data will not be permitted.

From where data/document is obtainable
Applicant investigators could contact us with email addresses.

What processes are involved for a request to access data/document
The applicant will receive an email with the file containing the IPD within one month of requesting it.

Comments