

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 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 \geq 160 and DBP \geq 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
Ermiya Mousavi
Street address
Emamreza Hospital Square, Ibn Sina Ave, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
MDS.Dean@mums.ac.ir

2

Recruitment center
Name of recruitment center
Ghaem Hospital

Full name of responsible person
Ermiya Mousavi
Street address
Ahmad Abad Ave, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3840 0001
Email
b.ghaem@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresraech@mums.ac.ir
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

Street address

Ahmad Abad Ave, Ghaem Hospital, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3859 4082

Email

majidiMR@mums.ac.ir

Person responsible for scientific 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

Street address

Ahmad Abad Ave, Ghaem Hospital, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3859 4082

Email

majidiMR@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed ermia Mousavi mohammadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Ahmad Abad Ave, Ghaem Hospital, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3859 4082

Fax

Email

ermiamsm@gmail.com

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