Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Topical Intranasal Tranexamic Acid for Stopping Nose Bleeding in Patients with Epistaxis in the ENT Emergency Department

Protocol summary

Study aim

The aim of the study is to evaluate the effectiveness of topical intranasal TXA in reducing the need for long- term anterior nasal packing in adult patients presenting to the ED with spontaneous atraumatic epistaxis.

Design

A phase 3 randomized, single-blind, parallel-group controlled single-center trial on 240 participants.Randomization will be done by computerized block randomization by SPSS version 23.

Settings and conduct

This single-blind (only the participants are blinded) randomized (with block randomization method) controlled trial will be carried out on 240 patients with spontaneous atraumatic anterior epistaxis presenting to ENT ED of Khalili Hospital affiliated to Shiraz University of Medical Sciences, Iran. The patients will be divided into two groups: one group receives topical intranasal tranexamic acid and the other group does not.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18 or over; presenting to the emergency department (ED) with spontaneous, atraumatic anterior epistaxis, unresolved with simple first aid. Exclusion criteria: hemodynamically unstable; allergy to tranexamic acid; a known nasopharyngeal, nasal cavity or paranasal malignancy; epistaxis caused by trauma; any known bleeding disorder.

Intervention groups

In the intervention group, cotton mesh soaked into tranexamic acid along with lidocaine and phenylephrine will be applied into the nose. In the control group, the cotton mesh will be soaked into lidocaine and phenylephrine alone.

Main outcome variables

Need for anterior nasal packing

General information

Reason for update

Regarding the fact that the clinical trial registered sooner than what the investigators expected, the study will be expected to start on 21 April 2021. Also, due to the busy ED, it is not practically possible to assess the time of stopping bleeding. Therefore, this outcome will not be measured in the trial. The investigators decided to change the trial from single-blinded to double-blinded. Also, recent use of any anticoagulant drug will be added to the exclusion criteria

Acronym

IRCT registration information

IRCT registration number: **IRCT20210403050815N1**
Registration date: **2021-04-10, 1400/01/21**
Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**
Update count: **3**

Registration date

2021-04-10, 1400/01/21

Registrant information

Name
reza jahangiri
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3629 1470
Email address
rjahangiri62@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Topical Intranasal Tranexamic Acid for Stopping Nose Bleeding in Patients with Epistaxis in the ENT Emergency Department

Public title
Topical Intranasal Tranexamic Acid in Epistaxis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 18 or over Presenting to the Ear, Nose, and Throat emergency department (ED) with spontaneous, atraumatic anterior epistaxis, unresolved with simple first aid

Exclusion criteria:
Hemodynamically unstable Known allergy to tranexamic acid Lacking capacity or unwilling to give consent Known nasopharyngeal, nasal cavity or paranasal malignancy Pregnancy Already undergone prehospital nasal packing Prisoners Epistaxis caused by trauma (excluding simple nose picking) Any Known bleeding disorders Any recent use of anticoagulation drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
Random numbers were generated through computerized block randomization using SPSS software version 23.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, care providers, investigators, outcome assessors, and data collectors will be blinded to the topically applied medications used for stopping bleeding. Data Safety and Monitoring Board and manuscript writers will be not blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of School of Medicine - Shiraz University of Medical Sciences

Street address
Zand St.

City
Shiraz

Province
Fars

Postal code
7194646861

Approval date
2020-11-16, 1399/08/26

Ethics committee reference number
IR.SUMS.MED.REC.1399.440

Health conditions studied

1

Description of health condition studied
Epistaxis

ICD-10 code
R04.0

ICD-10 code description
Epistaxis

Primary outcomes

1

Description
Need for use of anterior nasal packing

Timepoint
at any time during that ED attendance after initial management

Method of measurement
determined by clinical judgment

Secondary outcomes

1

Description
need for use of electrical cauterization

Timepoint
at any time during ED attendance after initial intervention

Method of measurement
determined by clinical judgment of physician

2

Description
rebleeding within 24 hours after presenting to ED
Timepoint
within 24 hours after treatment
Method of measurement
self-statement of the patient with telephone call

3

Description
rebleeding within 1-7 days after presenting to ED
Timepoint
1-7 days after presenting to ED
Method of measurement
self-statement of the patient with telephone call

4

Description
ED stay more than 2 hours
Timepoint
from presenting to ED to leaving the hospital
Method of measurement
This outcome variable will be evaluated and reported as a qualitative variable. The patients who have been discharged from ED after 2 hours from the presentation will be considered as positive cases for this variable.

Intervention groups

1

Description
Intervention group: In the intervention group, medicated cotton pledgets soaked into IV formulation of tranexamic acid (tranexip, 500mg/5ml, Caspian Tamin) plus phenylephrine nasal drop (Nasopherin, 0.5%, Sina Darou) plus lidocaine solution (10%, Iran Darou) will be inserted in each nostril for 15 minutes for initial epistaxis management in the ED.
Category
Treatment - Drugs

2

Description
Control group: In the control group, medicated cotton pledgets soaked into phenylephrine nasal drop (Nasopherin, 0.5%, Sina Darou) plus lidocaine solution (10%, Iran Darou) will be inserted in each nostril for 15 minutes for initial epistaxis management in the ED.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Sciences
Full name of responsible person
Milad Hosseinialhashemi
Street address
Zand St.
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
info@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Milad Hosseinialhashemi
Street address
Zand St
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Milad Hosseinialhashemi

Position
Resident

Latest degree
Medical doctor

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

Street address
Chamran blvd.

City
Shiraz

Province
Fars

Postal code
7194646861

Phone
+98 71 3626 7225

Email
miladhashemi88@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Milad Hosseinialhashemi

Position
Resident

Latest degree
Medical doctor

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

Street address
Chamran blvd.

City
Shiraz

Province
Fars

Postal code
7194646861

Phone
+98 71 3626 7225

Email
miladhashemi88@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Milad Hosseinialhashemi

Position
Resident

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Email
miladhashemi88@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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