

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

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

miladhashemi88@gmail.com

Contact

Name of organization / entity
Shiraz University of Medical Sciences
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Position
Resident
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Person responsible for updating data

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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