# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jul 2026

## Comparison of topical tranexamic versus nasal tampon in epistaxis in patient who admit to Alzahra anh Kashani Hospital of Isfahan

## Protocol summary

**Study aim**
Evaluation of the therapeutic effect of topical tranexamic acid in control of epistaxis of nasal bleeding

**Design**
A clinical trial with 162 sample size with a control group, with parallel, double-blinded, randomized groups

**Settings and conduct**
The study population consisted of all epistaxis patients referred to the emergency department of Alzahra and Kashani hospitals in Isfahan. These were randomly selected. Demographic and clinical data including age, gender, history of cardiovascular disease, history of nasal bleeding, systolic and diastolic blood pressure and mean arterial and heart rate were recorded. Patients were divided into 4 groups. After intervention in each group, patients remained in the emergency department for up to 30 minutes and were evaluated every 5 minutes for recording bleeding time. The criteria for cessation of bleeding are, according to your physician, the absence of any bleeding. In addition, the patient's status was monitored by telephone over the first 24 hours and the first week after intervention and side effects such as nausea and vomiting until one week after hospital discharge. Patient satisfaction level was also scored based on a score of 0 to 3.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Anterior epistaxis with idiopathic etiology; Exclusion criteria: Posterior epistaxis; A history of bleeding disorders such as thrombocytopenia, hemophilia and platelet disorders; Seizure; Arterial or intravenous thrombosis;

**Intervention groups**
We have three intervention groups. In the first group as control group, patients were treated with tampon. The second group of tranexamic acid is injected into the bleeding nasal canal. And the third group uses in addition to tranexamic acid injectable tampon, which is fatty tetracycline ointment.

**Main outcome variables**
Stop the bleeding, Rebleeding

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160130026253N3**
Registration date: **2020-01-16, 1398/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-16, 1398/10/26**
Update count: **0**

**Registration date**
2020-01-16, 1398/10/26

**Registrant information**

**Name**
Alireza Abootalebi Ghahnavieh

**Name of organization / entity**
Isfahan University of medical sciences, Emergency Department, Isfahan, I. R, Iran.

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**
Vice chancellor for research,Isfahan University of Medical Sciences

**Expected recruitment start date**
2019-03-21, 1398/01/01

**Expected recruitment end date**
2021-03-19, 1399/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of topical tranexamic versus nasal tampon in epistaxis in patient who admit to Alzahra anh Kashani Hospital of Isfahan

**Public title**

Comparison of topical tranexamic versus nasal tampon in epistaxis

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

patients with unilateral idiopathic anterior epistaxis

**Exclusion criteria:**

Posterior epistaxis A history of bleeding disorders such as thrombocytopenia, hemophilia and platelet disorders Seizure Arterial or intravenous thrombosis Use of anticoagulants, platelets and aspirin

**Age**

From **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **162**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The study sample was randomly divided into three groups each by selective envelopes. Thus, each envelope containing one of the three A, B, C labels represented one of the groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drugs were placed in closed envelopes coded A and B and C without labeling and without the knowledge of the investigator.Patients and investigator were unaware of the kind of treatment in each envelope.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethic Committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezarjirib St, Isfahan

**City**

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**Province**

Isfehan

**Postal code**

8174673461

**Approval date**

2016-01-25, 1394/11/05

**Ethics committee reference number**

IR.MUI.REC.1394.3.880

## Health conditions studied

**1**

**Description of health condition studied**

Epistaxis

**ICD-10 code**

R04.0

**ICD-10 code description**

Epistaxis

## Primary outcomes

**1**

**Description**

Stop the bleeding

**Timepoint**

Every 5 minutes

**Method of measurement**

stopwatch

**2**

**Description**

Rate of rebleeding

**Timepoint**

During the first 24 hours as well as the first week after intervention

**Method of measurement**

stopwatch

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group 1: In this group 15 cm gas was

immersed in tranexamic acid at a concentration of 500 mg / ml in 5 ml and placed in the bleeding nasal duct.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients were treated with tamponine, which was oily tetracycline ointment and remained in the nasal duct for 3 days.

**Category**

Treatment - Devices

**3**

**Description**

Intervention second group: In this group, 15 cm gas was immersed in tranexamic acid at a concentration of 500 mg / ml and placed in the bleeding nasal duct. It was placed in the nasal canal for 3 days.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Emergency Department of Isfahan Alzahra

**Full name of responsible person**

Alireza Abootalebi Ghahnavieh

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**2**

**Recruitment center**

**Name of recruitment center**

Kashani Hospital

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ziba Farajzadegan

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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**

Esfahan 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**

Isfahan University of medical sciences, Emergency Department, Isfahan, I. R, Iran

**Full name of responsible person**

Alireza Abootalebi Ghahnavieh

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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**
No - There is not 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**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Information about the main outcome can be shared.

**When the data will become available and for how long**
Start the access period 6 months after publishing the results

**To whom data/document is available**
Researchers working in academia

**Under which criteria data/document could be used**
Use data to complete clinical trial studies

**From where data/document is obtainable**
Email: A_abootalebi@yahoo.com

**What processes are involved for a request to access data/document**
After the investigation of researcher request and presentation of required documents will be accessible.

**Comments**