

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

camparison of local Tranexamic Acid with anterior nasal packing in control of epistaxis in patients with antiplatelets therapy(ASA, Plavix) whom referring with anterior nasal bleeding.

Protocol summary

Summary

Efficacy of topical Tranexamic Acid in control of anterior epistaxis by anterior nasal tampons is evaluated previously. This randomized, single-blind, multi-center study would be performed on patients referred to Shariati and Sina Hospitals with complaints of epistaxis from October 2015 till April 2016. Exclusion Criteria: Trauma patients; history of anticoagulants drug consumption; Inherited bleeding disorders; Hemophiliacs; Inherited platelet disorders; Shock; Lack of consent; patients with visible bleeding vessel; INR>1.5 and history of renal disease. In the intervention group, a 15cm-cotton wick dipped in Acid Tranexamic is used. The wick is placed in the nasal cavity and the bleeding is evaluated and recorded in 5-minute intervals. The bleeding recurred in 24 hours and one week later will be assessed. Patient's discharge time from the emergency department is also recorded. In the second group (control group) common methods are used to control the bleeding, which are shrinkage of the anterior nasal and then placing the tampon. All variables mentioned in the first group are recorded in this group, too. If bleeding is not controlled in Acid Tranexamic group, then the common method for controlling the bleeding is used. Finally, patient's satisfaction of treatment is evaluated using a numerical scoring system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509088872N9**

Registration date: **2015-09-25, 1394/07/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-25, 1394/07/03

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2719

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences -Faculty of Medicine

Expected recruitment start date

2015-10-12, 1394/07/20

Expected recruitment end date

2016-04-01, 1395/01/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

camparison of local Tranexamic Acid with anterior nasal packing in control of epistaxis in patients with antiplatelets therapy(ASA, Plavix) whom referring with anterior nasal bleeding.

Public title

effectiveness of local Tranexamic Acid on Epistaxis Control in patients with antiplateletes therapy(ASA,

plavix)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: All patients with epistaxis and history of consumption of ASA and Plavix whom referring to the emergency department. Exclusion Criteria: Trauma patients; history of anticoagulants drug consumption; Inherited bleeding disorders; Hemophiliacs; Inherited platelet disorders; Shock; Lack of consent; patients with visible bleeding vessel; history of renal disease; INR> 1.5

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics review committee of Tehran University of Medical Sciences-Faculty of Medicine, Dr Akbar fotouhi

Street address

floor 5, NO 226, Poursina avenue, Ghods avenue, Enghelab square, Tehran

City

Tehran

Postal code

Approval date

2015-08-26, 1394/06/04

Ethics committee reference number

IR.TUMS.REC.1394.660

Health conditions studied

1

Description of health condition studied

Epistaxis
ICD-10 code
R04.0
ICD-10 code description
خونریزی از بینی

Primary outcomes

1

Description

Bleeding control time

Timepoint

every 5 minutes from the start point until the bleeding stops

Method of measurement

measured by stopwatch, per minute

Secondary outcomes

1

Description

bleeding recurrence

Timepoint

first 24 hours and the first week

Method of measurement

measured by watch

2

Description

patient's satisfaction

Timepoint

within discharge

Method of measurement

by VAS measurement system (10 points mark)

Intervention groups

1

Description

Tranexamic Acid: Ampoule, 100mg/ml, Local, the wick is soaked in 5cc of solution

Category

Treatment - Drugs

2

Description

Epinephrine 1/100000 and Lidocaine 2%, Solution, Local, the wick is soaked in 5cc of solution.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Sina and Shariati Hospitals

Full name of responsible person

Dr Morteza Saeedi

Street address

Sina Hospital (Hsanabad Square)and Shariati Hospital(beside Eghtesad university; Al Ahmad high way; North Kargar avenue) Emergency Departement

City

Tehran

Postal code**Phone**

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Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Morteza Saeedi

Position

Emergency Medicine Department; Associtet Professor of emergency medicine

Other areas of specialty/work**Street address**

Emergency Department, Shariati Hospital, North-Amir abaad, Tehran, Iran.

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences -Faculty of Medicine

Full name of responsible person

Dr Shahin Akhundzade

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Vice Chancellor for Research of Tehran ,University of Medical Sciences, Poursina Avenue, Enghelab Square

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences -Faculty of Medicine

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

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Dr. Morteza Saeedi

Position

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Morteza Saeedi

Position

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Other areas of specialty/work**Street address**

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Tehran

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty