Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effect of local and intravenous Tranexamic Acid and Phenylephrine Shrink on control of bleeding in patients with epistaxis: a double-blind randomized clinical trial

Protocol summary

Study aim
To compare the effect of local and intravenous Tranexamic Acid and Phenylephrine Shrink on control of bleeding in patients with epistaxis

Design
This is a double-blind randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients with epistaxis who will refer to Besat Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 70 years; Epistaxis
Exclusion criteria: Hypertension; Contraindication of Phenylephrine; A history of coagulopathy; A history of nasal surgery

Intervention groups
Intervention group 1: Injection of Tranexamic Acid 1 gr single dose Intervention group 2: Use of local tampon stained with Tranexamic Acid 500 mg once Intervention group 3: Use of Phenylephrine Shrink drops 0.5% once

Main outcome variables
Assessing the bleeding rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N244**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **prospective**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date
2018-10-20, 1397/07/28

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of local and intravenous Tranexamic Acid and Phenylephrine Shrink on control of bleeding in patients with epistaxis: a double-blind randomized clinical trial

Public title
Comparison of the effect of local and intravenous Tranexamic Acid and Phenylephrine Shrink on control of bleeding in patients with epistaxis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 70 years; Epistaxis
Exclusion criteria:
Hypertension; Contraindication of Phenylephrine; A history of coagulopathy; A history of nasal surgery
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on every two sheets the name of each treatment. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will be unaware of the type of intervention. In addition, the physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Postal code
6517838695
Approval date
2018-09-01, 1397/06/10
Ethics committee reference number
IR.UMSHA.REC.1397.417

Health conditions studied

1

Description of health condition studied
Epistaxis
ICD-10 code
R04.0
ICD-10 code description
Epistaxis

Primary outcomes

1

Description
Assessing the bleeding rate
Timepoint
5 and 10 minutes after intervention
Method of measurement
By physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Injection of Tranexamic Acid 1 gr single dose
Category
Treatment - Drugs

2

Description
Intervention group 2: Use of local tampon stained with Tranexamic Acid 500 mg once
Category
Treatment - Drugs

3

Description
Intervention group 3: Use of Phenylephrine Shrink drops 0.5% once

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Hamedan 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
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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