

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

2018-10-20, 1397/07/28

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

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City

Hamadan

Province

Hamadan

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

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

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Dr Sadegh Chaeichi

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

sadeghchaeichi@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street addressHamadan University of Medical Sciences, Shahid
Fahmideh Ave**City**

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Sadegh Chaeichi

Position

Emergency Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

sadeghchaeichi@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Rasoul Salimi

Position

Emergency Medicine Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

rasoulsl@yahoo.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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