

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of prophylactic effect of tranexamic acid capsule on nasal hemorrhage in patients with epistaxis

Protocol summary

Study aim

Determination of the prophylactic effect of Tranexamic acid capsule in controlling nasal hemorrhage in patients with epistaxis

Design

Non-randomized clinical trial with parallel groups, with control group, Double blind, sample size 100

Settings and conduct

All patients with epistaxis who were referred to Zahedan Khatam Hospital clinic were included by convenience sampling method. Both analgesics were in boxes A and B, and only the physician responsible for conducting the program (supervisor) was aware of the drug content of each group. In the control group, drops of NaCl (3 times a day, 5 drops per week for one week) and ointment of vitamin A (three times daily for one week) were administered and in the intervention group, drops of NaCl (3 times A daily dose of 5 drops per week for one week) and vitamin A ointment (twice daily for one week) with Tranexamic acid 500 mg every 8 hours for one week.

Participants/Inclusion and exclusion criteria

The subjects who participated in the study were referred to the Clinic of Khatam Hospital in Zahedan from all individuals with epistaxis with an idiopathic cause.

Intervention groups

Control: Chloride and ointment drops of vitamin A were prescribed The intervention group received drops of sodium chloride and vitamin A ointment with tranexamic acid

Main outcome variables

Rebleeding within a month after the intervention;
Nausea; Vomiting; Satisfaction; Sinus and nose symptoms; Diarrhea; Abdominal pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039418N7**

Registration date: **2019-07-10, 1398/04/19**

Registration timing: **retrospective**

Last update: **2019-07-10, 1398/04/19**

Update count: **0**

Registration date

2019-07-10, 1398/04/19

Registrant information

Name

mohammad Ghena'at Pisheh Sanani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3343 1227

Email address

mohammad.ghenaat71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-04-21, 1398/02/01

Trial completion date

2019-04-21, 1398/02/01

Scientific title

Evaluation of prophylactic effect of tranexamic acid capsule on nasal hemorrhage in patients with epistaxis

Public title

Prophylactic effect of tranexamic acid capsule in controlling epistaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Insensitivity to the drugs used in the study Satisfaction to enter the study

Exclusion criteria:

Patients with seizure, arterial or venous thrombosis, leukemia, lymphoma, polycythemia vera, pregnant women Patients who have taken anticoagulants, anti-platelets and even aspirin

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients were treated using pharmacologic packages prespecified by the study supervisor (supervisor). The information gathering, patient assessment, and completion forms were carried out by the program implementer and assistant who were not aware of the contents of the packages; at the analysis stage Data were also analyzed by the design and implementation consultant's consultant who was not aware of the contents of the drug packs and only the group of patients (group 1 or 2) was identified for data analysis; therefore, the study was a three-blind study, and from the patient's entry phase in the study Until the study, data collection and analysis of data, the contents of the two drug groups were unclear.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Dr.Hesabi Square, Campus of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.ZAUMS.REC.1397.494

Health conditions studied

1

Description of health condition studied

Epistaxis

ICD-10 code

R04.0

ICD-10 code description

Epistaxis

Primary outcomes

1

Description

Patient satisfaction from treatment based on questionnaire

Timepoint

Every week from the start of treatment and up to one month after treatment

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 50 patients, drops of NaCl and vitamin A ointment with 500 mg tranexamic acid were administered every 8 hours a week.

Category

Treatment - Drugs

2

Description

Control group: For 50 patients, drops of NaCl and vitamin

A ointment every 8 hours for a week were prescribed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Hospital

Full name of responsible person

Dr. Gholamali Dashti Khudaki

Street address

Salamat Blvd, Persian Gulf Expressway

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9816743111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Dashti Khudaki

Street address

Dr.Hesabi square , Medical Sciences Campus

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Dashti Khudaki

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available