

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of Efficacy of Aluminum Chloride Gel with Topical Phenylephrine Drops in Control of Epistaxis

Protocol summary

Study aim

Compare the efficacy of aluminum chloride gel / 25% with phenylephrine drop for control of bleeding in patients with idiopathic epistaxis in the emergency department.

Design

Randomized, parallel group, double-blind, placebo-controlled clinical trial

Settings and conduct

The study population include, patients with epistaxis referring (without age restriction) to emergency department of Al-Zahra and Kashani Hospitals in Isfahan, then they are divided into two groups. Sample size is calculated as 59 in each group, phenylephrine drop group and aluminum-chloride gel (0.25%) group. Medications are prepared by a nurse who is not involved in treatment and is provided to the treatment team. After the interventions, patients in both groups will remain in the emergency department for up to 30 minutes and will be monitored every 5 minutes to record bleeding control time. Also, the cut-off bleeding time will be recorded in the first 10 minutes, and after discharge, patients will be monitored for recurrence of bleeding within one day (24 hours). Finally, the patients' satisfaction rate will be measured based on a score of 0 (dissatisfaction) of up to 10 (complete satisfaction).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Entry Criteria: Patients with anterior nasal bleeding and idiopathic cause will be included in the study. Exclusion criteria: The cause of nosebleedings due to posterior epistaxis or trauma, and with a history of bleeding disorders such as thrombocytopenia and platelet disorders

Intervention groups

In the intervention group, epistaxis was controlled with aluminum-chloride gel (0.25%). In the control group, phenylephrine drop will be used for the treatment of epistaxis.

Main outcome variables

Epistaxis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038549N6**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Farhad Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 8804

Email address

drfarhadheydari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Efficacy of Aluminum Chloride Gel with Topical Phenylephrine Drops in Control of Epistaxis

Public title
Efficacy of the topical Aluminum chloride 25/% gel in treatment of Epistaxis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Anterior Epistaxis
Exclusion criteria:
Trauma Posterior epistaxis History of bleeding disorders

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **118**

Randomization (investigator's opinion)
Randomized

Randomization description
A computer-generated random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs in two groups A and B are prepared by a nurse who is not involved in the treatment of patients. In one group, phenylephrine drops and in the other group aluminum chloride gel (0.25%) will be used to control of epistaxis. Patients and nurses are unaware of the contents of the medications. Also, the investigator and the data collector are not aware of the contents of the drugs.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical

Sciences
Street address
Alzahra hospital, Sofe Ave., Shahid Keshvari Blvd.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Approval date
2017-07-25, 1396/05/03
Ethics committee reference number
ir.mui.rec.1390.3.688

Health conditions studied

1

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

Primary outcomes

1

Description
Epistaxis control
Timepoint
Every 5 minutes
Method of measurement
Physical exam

Secondary outcomes

1

Description
Time to stop nose bleeding
Timepoint
Up to 30 minutes
Method of measurement
Physical exam

2

Description
Rebleeding
Timepoint
Up to 24 hours
Method of measurement
Physical exam

3

Description
Patient Satisfaction
Timepoint
Up to 30 minutes

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Aluminum chloride gel (0.25%) will be used to control nosebleedings.

Category

Treatment - Drugs

2

Description

Control group: Phenylephrine drop will be used to control epistaxis.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Saeed Majidinejad

Street address

Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

smajidinejad@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Saeed Majidinejad

Street address

Kashani Hospital, kashani Street

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3233 0091

Email

smajidinejad@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjooy javanmard

Street address

Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 0048

Email

drfarhadheydari@gmail.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Mehrnaz Sadat Hakamian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Emergency department, Alzahra Hospital, Sofeh Ave., Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone
+98 313202020
Fax
Email
radicalnet524@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Saeed Majidinejad
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Department of Emergency Medicine, Al-Zahra Hospital, Sufeh Ave.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2085
Fax
Email
smajidinejad@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Farhad Heydari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Department of Emergency Medicine, Al-Zahra Hospital, Sufeh Ave.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3776 9818
Fax
Email
drfarhadheydari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no extra data.

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