Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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
Isfehan
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 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
Isfehan
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
Isfehan
Postal code
8177777645
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
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
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
Isfehan
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
Isfehan
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
Isfehan
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