Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of topical timolol on recurrent epistaxis: a clinical trial

Protocol summary

Study aim
Determining the effectiveness of timolol nasal spray in frequent epistaxis patients

Design
The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 3 on 35 patients in each group, making a total of 70 patients. Random assignment by card was used for randomization.

Settings and conduct
This study will be conducted in 2024 and 2025 at Al-Zahra Hospital in Isfahan under the supervision of Isfahan University of Medical Sciences. People participating in this study will be divided into 2 groups. In this study, the patient and the statistician are not aware of the grouping of patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: History of recurrent epistaxis with at least 4 episodes in the last four weeks and at least one episode in the last week; Exclusion criteria: Pregnancy and breastfeeding; asthma or chronic lung disease; coagulation problems like hemophilia; hypotension; heart failure; bradycardia; pheochromocytoma or severe peripheral circulatory disorders; Receiving calcium antagonists or antiarrhythmics or clonidine, lidocaine; beta blockers fluctafenine, sultopride or amiodarone; anticoagulants; timolol sensitivity; Nose surgery in the last month

Intervention groups
People participating in this study will be divided into 2 groups. The first group as an intervention group will be treated with half percent timolol nasal spray made by Raha Pharmaceutical Company and the second group will be treated with placebo made by the Faculty of Pharmacy. The method of treatment in both groups will be similar and 2 times a day for 4 weeks.

Main outcome variables
Epistaxis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240327061371N1**
Registration date: **2025-03-02, 1403/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-02, 1403/12/12**
Update count: **0**

Registration date
2025-03-02, 1403/12/12

Registrant information
Name
Afrooz Eshaghian
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3233 0092
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-31, 1403/08/10
Expected recruitment end date
2025-03-20, 1403/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of topical timolol on recurrent epistaxis: a clinical

trial

Public title
Effect of topical timolol on recurrent epistaxis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
History of recurrent epistaxis with at least 4 episodes in the last four weeks
Exclusion criteria:
Pregnancy Having bronchial asthma or chronic lung disease Suffering from diseases that cause coagulation problems, such as hemophilia Patients with low blood pressure Having pheochromocytoma or severe peripheral blood circulation disorders Receiving calcium antagonists History of nose surgery in the last month breastfeeding Having chronic lung disease Patients with heart failure Patients with bradycardia Patients with other cardiac contraindications for beta-blockers Patients with peripheral vascular circulation dysfunction Receiving amiodarone Receiving antiarrhythmics Receiving clonidine Receiving lidocaine Receiving beta blockers Receiving fluctafenine Receiving soltopride Hypersensitivity to timolol Use of anticoagulants
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random: Random allocation rule will be used for random sampling. In this way, 35 cards of the same shape with the name of group A and 35 cards of the same shape with the name of group B are thrown into a container. Then the cards are randomly removed from the container without replacement and the created sequence is recorded, and sampling is also done from Between eligible patients will be based on this sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blinding: The placebo will be in the form of normal saline by the pharmacist's colleague in the same containers as the drug spray , which will be poured into the containers and opened after the completion of the coding study. patient and statistician are blinded. In this way, eligible patients referring to otolaryngology outpatient clinics will be assigned to group A or B based on the rule of random assignment. The attending physician is aware of the grouping (A = timolol spray B = placebo spray), the patient will be informed about the procedure based on the explanation of the intervention method and obtaining informed consent, but he does not know the allocation to the study group. The groups will not be notified and it only knows A and B groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Medicine - Isfahan University of Medical Sciences
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, hezar jarib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2024-10-12, 1403/07/21
Ethics committee reference number
IR.MUI.MED.REC.1403.260

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
Timepoint
Before the intervention and 2 weeks, 4 weeks, and 8 weeks after the intervention
Method of measurement
History taking

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: half percent timolol nasal spray manufactured by Raha Pharmaceutical Company, one puff in each nostril twice a day for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Normal saline nasal spray made by Faculty of Pharmacy, one puff in each nostril twice a day for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Atefeh Sharifi
Street address
Alzahra hospital, Hezarjarib street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
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Esfahan University of Medical Sciences, Hezarjarib Street
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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
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
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Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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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

No more information

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