

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 fluclofenazine, 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

Afroz Eshaghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 0092

Email address

afroozeshaghian@med.mui.ac.ir

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 flutafenine 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

Isfahan

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

City

Isfahan

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Isfahan

Postal code

75731-81746

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sharifatefeh7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Esfahan University of Medical Sciences, Hezarjarib Street

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8174675731

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research@mui.ac.ir

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

Afroz Eshaghian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Kashani Hospital, Kashani St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Afroz Eshaghian

Position

assistant Professor

Latest degree

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Person responsible for updating data

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Full name of responsible person

Afroz Eshaghian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Kashani Hospital, Kashani St.

City

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