

# 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

##### Province

Isfahan

##### Postal code

75731-81746

##### Phone

+98 31 3822 0000

##### Email

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

##### City

اصفهان

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3668 7898

#### Email

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.

##### City

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##### Province

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##### Postal code

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##### Phone

+98 31 3233 0091

##### Email

afroozeshaghian@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

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Esfahan University of Medical Sciences

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Afroz Eshaghian

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assistant Professor

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Specialist

##### Other areas of specialty/work

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**Person responsible for updating data**

**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.

**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