

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of oral Tizanidine in severity of pain after Septoplasty, in two groups of drug and placebo

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of oral Tizanidine in the severity of pain after septoplasty

##### Design

Double blind randomized controlled trial. People doing postoperative care and outcome (severity of pain) assessment, were blinded. Sample size was 70. Participant were selected by convenience sampling and were later allocated to two groups randomly.

##### Settings and conduct

This study will be conducted in Shafa Kerman hospital on 70 eligible patients in ENT who are candidates for septoplasty surgery. The surgeon and the anesthetist and the pain assessor resident will be blind to the prescription. 35 patients per arm were calculated and the total sample size was 70 patients. Patients will be randomly divided into two groups by using the random numbers table. This study was first approved by the Ethics Committee of Kerman University of Medical Sciences as the approved proposal, and then a written consent form will be obtained from all patients participating in the post-briefing study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 50 years of age in stage 1 and 2 of ASA Exclusion Criteria: 1-Stomach ulcer 2- Use of immune suppressants and corticosteroids 3- Contraindications to Tizanidine 4- Cases that need to be treated by different anesthesia or surgery methods 5- Drug addict patients 6- Certain patients such as kidney failure or liver failure 7- Patients with ASA 3

##### Intervention groups

Intervention: Tizanidine 4 mg , 2 hours before surgery  
Control: Vitamin B1 tablets 100 mg, 2 hours before surgery

##### Main outcome variables

The severity of post-surgery pain by pain Visual Analogue Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190921044831N1**

Registration date: **2019-12-27, 1398/10/06**

Registration timing: **retrospective**

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

##### Registration date

2019-12-27, 1398/10/06

##### Registrant information

##### Name

Farima Minaee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3893 4320

##### Email address

minaee.farima@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-04-09, 1393/01/20

##### Expected recruitment end date

2015-03-11, 1393/12/20

##### Actual recruitment start date

2014-04-09, 1393/01/20

##### Actual recruitment end date

2015-03-11, 1393/12/20

##### Trial completion date

2015-03-11, 1393/12/20

##### Scientific title

Comparison of the effectiveness of oral Tizanidine in severity of pain after Septoplasty, in two groups of drug and placebo

#### Public title

"Effect of Tizanidine in reducing the pain of after septoplasty"

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with septoplasty class 1 or/and 2 ASA Not history of gastric ulcer Not history of using corticosteroids or other immune system suppressors

##### Exclusion criteria:

Allergy to Tizanidine Age < 18 y or >50 y Re-Septoplasty Sinorhinoplasty Contraindication of Tizanidine therapy Cases that need to be treated differently by anesthesia or surgery Addiction Hepatic or renal disorder Cases of ASA 3

#### Age

From **18 years** old to **50 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

#### Sample size

Target sample size: **71**

Actual sample size reached: **71**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

simple randomization by Randomised number table

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Surgeons and physicians who were assessing pain severity and anesthesia survivors and also patients were blinded

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Kerman University of Medical Sciences Ethics committee

#### Street address

Haft Bagh Alavi Highway

#### City

Kerman

#### Province

Kerman

#### Postal code

76169-13555

#### Approval date

2009-09-06, 1388/06/15

#### Ethics committee reference number

IR.KMU.REC.1388.236

### Health conditions studied

#### 1

##### Description of health condition studied

Deviation of nasal septum

##### ICD-10 code

J34.2

##### ICD-10 code description

Deflection or deviation of septum (nasal)(acquired)

### Primary outcomes

#### 1

##### Description

Pain of after septoplasty surgery

##### Timepoint

After 4, 8 and 24 hours after surgery

##### Method of measurement

Visual Analogue Scale

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Oral Tizanidine tablet 4 mg (Hakim Pharmacy Company) 2 hours before surgery

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: Placebo, Oral Vitamin B1 100 mg tablet (Poursina Pharmacy Company) 2 hours before surgery

##### Category

Treatment - Drugs

### Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Shafa Kerman hospital

**Full name of responsible person**

Aliasghar Arabi

**Street address**

Ear, Throat and Nose & Head and Neck Surgery  
Department, Shafa hospital, Kerman University of  
Medical Science, Kosar Blvd, Kerman, Iran.

**City**

Kerman

**Province**

Kerman

**Postal code**

۷۶۱۸۷۵۱۱۵۱

**Phone**

+98 34 3211 5780

**Email**

a\_arabi@kmu.ac.ir

**Web page address**

http://kmu.ac.ir/fa/sh

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kermen Medical University, Chancel of research

**Full name of responsible person**

Ali asghar Arabi Mianroodi

**Street address**

Ear, Throat and Nose & Head and Neck Surgery  
Department, Shafa hospital, Kerman University of  
Medical Science, Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

۷۶۱۸۷۵۱۱۵۱

**Phone**

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**Email**

a\_arabi@kmu.ac.ir

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermen Medical University, Chancel of research

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

علی اصغر عربی

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Kerman University of Medical Sciences, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran

**City**

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**Postal code**

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**Phone**

+98 34 3132 5856

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Aliasghar Arabi Mianroodi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Aliasghar Arabi Mianroodi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The results of this clinical trial will be sent to the authored journals for publication and after publication, if any researchers who wish to cite this article requests, the coded information without any participants' personal information; will be sent.

**When the data will become available and for how long**

start of accessibility will be 3 months after publication

**To whom data/document is available**

محققینی که به طور معتبر قصد ارجاع به مقاله را دارند

**Under which criteria data/document could be used**

The results and preliminary data collected are confidential and coded by researchers who intend to refer to this article.

**From where data/document is obtainable**

Formally request the corresponding author of the article.

**What processes are involved for a request to access data/document**

The applicant firstly proves his credibility as a researcher by introducing himself and his ORCID code, and then formally communicate with the corresponding author of the paper, explaining the title of his research and the purpose of obtaining this article's information and makes his request. After consulting with other authors, the author in charge of providing the researcher's request should be sure of the confidentiality of the data is maintained.

**Comments**