Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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.

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a_arabi@kmu.ac.ir

Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermen Medical University, Chancel of research

Full name of responsible person
Ali asghar Arabi Mianroodi

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

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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
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
Assisstant professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Person responsible for updating data

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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