

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Investigation the effect of local anesthesia in nasal mucosa with %0.5 tetracaine drop on hemodynamic changes, bleeding during surgery and pain after surgery in septoplasty.

Protocol summary

Summary

The aim of this study is Investigation the effect of local anesthesia in nasal mucosa with %0.5 tetracaine drop on hemodynamic changes, bleeding during surgery and pain after surgery in septoplasty. This study is a double blind clinical trial. This study is done on patients candidate for septoplasty who are 15-35 years old with ASA I and II. Exclusion criteria: History of hypersensitivity to tetracaine or other local anesthetic drugs, history of using analgesics more than 5 days continuously in last month, history of drug abuse. weight more than 100 kg or less than 30kg, history of hypertension. Sample size is 62. Patients are divided into two groups. In the first group, dipped cotton in 10 drops of %0.5 tetracaine is put in each nasal cavity. in the second group, dipped cotton in normal saline is put in each nasal cavity. this study has down between 22/12/2013 and 20/11/2014. The outcomes of study are heart rate, blood pressure, restlessness and pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505266252N8**

Registration date: **2015-07-17, 1394/04/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-17, 1394/04/26

Registrant information

Name

Soroush Amani

Name of organization / entity

Shahrekord University of Medical Sciences

Country

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samani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences.

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-11-20, 1393/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of local anesthesia in nasal mucosa with %0.5 tetracaine drop on hemodynamic changes, bleeding during surgery and pain after surgery in septoplasty.

Public title

Investigation the effect of local anesthesia in nose with %0.5 tetracaine drop on blood pressure, bleeding during surgery and pain after surgery in septoplasty.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The 15-35 years old patients with ASA I and II that candidate for septoplasty. Exclusion criteria: History of hypersensitivity to tetracaine or other local

anesthetic drugs, history of using analgesics more than 5 days continuously in last month, history of drug abuse. weight more than 100 kg or less than 30kg, history of hypertension.

Age

From **15 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahrekord University of Medical Sciences

Street address

Kashani Avenue, Shahrekord

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Shahrekod

Postal code

8815713471

Approval date

2013-11-27, 1392/09/06

Ethics committee reference number

1805

Health conditions studied**1****Description of health condition studied**

Septal deviation

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes**1****Description**

Systolic blood pressure

Timepoint

5 minute before anesthesia, 10, 15 and 20 minute after anesthesia

Method of measurement

with manometer

2**Description**

Diastolic blood pressure

Timepoint

5 minute before anesthesia, 10, 15 and 20 minute after anesthesia

Method of measurement

with manometer

3**Description**

Pulse rate

Timepoint

5 minute before anesthesia, 10, 15 and 20 minute after anesthesia

Method of measurement

with pulse oxymeter

Secondary outcomes**1****Description**

pain and restlessness

Timepoint

10 minutes after entrance to recovery and 70 minutes after end of surgery

Method of measurement

VAS questionnaire

Intervention groups**1****Description**

In the first group, dipped cotton in 10 drops of %0.5 tetracaine is put in each nasal cavity.

Category

Treatment - Drugs

2**Description**

in the second group, dipped cotton in normal saline is put in each nasal cavity.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Soroush Amani MD

Street address

Shariati Avenue, Shahrekord

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Mahmood Mobasheri MD

Street address

Kashani Avenue, Shahrekord

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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

Shahrekord University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

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Otolaryngologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty