

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of Labetalol and Nitroglycerin in control of blood pressure and bleeding reduction in septorhinoplasty surgery

Protocol summary

Summary

Purpose: Comparison between Nitroglycerin and Labetalol on bleeding during nasal surgery. Design and criteria: This study is prospective, randomized and clinical trial. Seventy patients over 16 years were randomly in two groups. The first group received nitroglycerin, the nitroglycerin dose rate of 5 mcg / min every 3 to 5 minutes, then to the extent prescribed by 5 mcg / min was added. They received labetalol, the starting dose is 5 mg in labetalol group. And to establish anti-hypertension effect desired, can be 5 to 10 mg every 5 minutes once received. The surgeon and patients are blinded about the type of drug. Inclusion criteria: candidate for nasal surgery; American Society of Anesthesiology (ASA) I and II Exclusion criteria: history of cardiovascular disease; previous hypertension; liver or kidney disease; hemoglobin below 10; coagulation disorders; receiving aspirin or medicines bleeding. Primary and secondary outcome: mean arterial blood pressure, volume of bleeding, heart rate, need for additional drug. Time of measurement: before induction, every 5 minutes to 75 minutes, after induction, during and end of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021712094N4**

Registration date: **2014-05-24, 1393/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-24, 1393/03/03

Registrant information

Name

Majid Razavi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 110 8630

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Science

Expected recruitment start date

2013-12-06, 1392/09/15

Expected recruitment end date

2014-04-09, 1393/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Labetalol and Nitroglycerin in control of blood pressure and bleeding reduction in septorhinoplasty surgery

Public title

Comparison of Labetalol and Nitroglycerin in control of blood pressure and bleeding reduction in septorhinoplasty surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: candidate for nasal surgery; American Society of Anesthesiology (ASA) I and II Exclusion criteria:

history of cardiovascular disease; history of hypertension; liver or kidney disease and coagulation disorders; hemoglobin below 10 ; receiving aspirin or other anticoagulation's before surgery

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

Postal code

Approval date

2013-11-30, 1392/09/09

Ethics committee reference number

911214

Health conditions studied

1

Description of health condition studied

nasal surgery

ICD-10 code

Y60.0

ICD-10 code description

Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care

Primary outcomes

1

Description

Mean arterial blood pressure

Timepoint

Before induction, Every 5 minutes to 75 minutes, after induction, during surgery and end of surgery

Method of measurement

Non-invasive monitoring of blood pressure

Secondary outcomes

1

Description

Volume of bleeding

Timepoint

Before induction, every 5 minutes to 75 minutes, after induction, during surgery and end of surgery

Method of measurement

Total gauze consumption and suction

2

Description

Heart rate

Timepoint

Before induction, every 5 minutes to 75 minutes, after induction, during surgery and end of surgery

Method of measurement

Hemodynamic monitoring

3

Description

Need for additional drug

Timepoint

Time of measurement: Before induction, every 5 minutes to 75 minutes, after induction, during surgery and end of surgery

Method of measurement

Based on the dose of drug

Intervention groups

1

Description

Intervention group 1 : they received nitroglycerin. The nitroglycerin dose rate of 5 mcg / min every 3 to 5 minutes, then to the extent prescribed by 5 mcg / min was added.

Category

Treatment - Drugs

2

Description

Intervention group 2 : they received labetalol, the starting dose is 5 mg in labetalol group. And to establish

anti-hypertension effect desired, can be 5 to 10 mg every 5 minutes once received

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr Majid Razavi

Street address

Imam Reza Hospital, Ibne Sina Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Science

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

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Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of Medical Science

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

Mashhad University of Medical Sciences

Full name of responsible person

Majid Razavi

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Razavi

Position

Assistant professor

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Fax

Email

Web page address

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