

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparison of Remifentanil and Labetalol infusion on intraoperative bleeding during Rhinoplasty surgery

Protocol summary

2014-02-23, 1392/12/04

Summary

Bring appropriate environment without bleeding in Rhinoplasty surgery , one of the main goals of anesthetic management of these patients is .One of the ways to achicve this goals to induce hypotension.60 Patients Male or Female ranging in age 18 to 50 years, with ASA 1-2 and blood pressure higher 100/70 mm/Hg,Heart rate above 40 minute candidate for Rhinoplasty surgery after obtaining permission from the Ethics Committee Shiraz University of Medical Sciences and informed consent are studied. Patients whose Blood pressure less than 100/70 mm/Hg ,Heart rate less than 40 minute , Heart disease ,Hypertension , Obestructive lung disease and Coagulation problems are to the Excluded. Patients were systematically and randomly divided into groups of 30 groups according to a table of random numbers are. Anesthesia is the same in both groups.After being anesthetized patients before surgical incision to maintain mean arterial pressure of 55-65 mm/Hg range Labetalol drug in 30 patients and 30 patients drug Remifentanil found. Beginning of the operation Mean Atrial Pressure (MAP) and Heart rate every 15 minute Record ;Bleeding during the operation by suction are collected.At the end of surgery with respect to the amount of blood in the suction and evaluate the quality of the surgical site by the surgen in the operative bleeding is cheeked.

Registrant information

Name

Abdoreza Gholami

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 0409

Email address

gholami_a@internet.sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of Remifentanil and Labetalol infusion on intraoperative bleeding during Rhinoplasty surgery

Public title

Blood loss in Rhinoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion:The patient with ASA 1-2 ;Men or Women between 18- 50 years; Disease without surgery Rhinoplasty;No patient had a history or physical exam of

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT20140223N115938**

Registration date: **2014-02-23, 1392/12/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

clotting problems; Blood pressure above then 100/70 mm/Hg ;Heart rate above then 40 mint;No history of Obstructive lung disease and Heart disease . Exclusion criteria: Patient with ASA above 2;Men or Women with Age less then 18 years and age above then 50 years; Repeat Rhinoplasty surgery ;Coagulation problem in history and physical exam;Blood pressure less then100/70mm/Hg;Heart rate less then 40 mint;History Obstructive lung disease and any Heart disease.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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

Shiraz University of Medical Sciences, Research

Street address

Research , Central Building Danesgah, Zand Blvd

City

Shiraz

Postal code

713451978

Approval date

2014-01-12, 1392/10/22

Ethics committee reference number

ct-p-92-5265

Health conditions studied

1

Description of health condition studied

q00-q99

ICD-10 code

q30-q34

ICD-10 code description

q30/9 -Congenital Malformation of nose , Unspecified

Primary outcomes

1

Description

The amount of intraoperative bleeding

Timepoint

The end of surgery

Method of measurement

Measurement of blood in the suction

2

Description

Evaluate the quality of the surgical site by the Surgen

Timepoint

The end of surgery

Method of measurement

Evaluate with table Boezaart by Surgen

Secondary outcomes

1

Description

Mean Artrial Pressure

Timepoint

During the study every 15 minute

Method of measurement

Pressure Set-Blood Pressure Monitoring

2

Description

Heart Rate

Timepoint

During the study every 15 minute

Method of measurement

Anesthesia Monitoring

Intervention groups

1

Description

After being anesthetized patients before surgical incision a group of 30 patients drug Labetalol with dose /4-3 mg/ kg/hr beginning to the end of the operation with a 50 cc syringe infusion pump operation will start. Mean Arterial Pressure (MAP) is in the range of 55-65 mm/Hg .In this area we have to see how much bleeding.

Category

Treatment - Drugs

2

Description

After being anesthetized patients before surgical incision a group of 30 patients drug Remifentanil with dose /1-3

mic/kg/min beginning to the end of the operation with a 50cc syringe infusion pump operation will start. Mean Arterial Pressure (MAP) is in the range of 55-65 mm/Hg .In the area we have to see how much bleeding.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dastgheb Hospital

Full name of responsible person

Abdoreza Gholami

Street address

Dastgheb Hospital , Hafez Ave

City

Shiraz

2

Recruitment center

Name of recruitment center

Mother Child Hospital

Full name of responsible person

Abdoreza Gholami

Street address

Mother Child Hospital, Reza Blvd

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraze University of Medical Sciences ,Research

Full name of responsible person

Dr.GHolamreza Hatam

Street address

Research, Central Buling Danesgah , Zand Blvd

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraze University of Medical Sciences ,Research

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**

Shiraz University of Medical Sciences

Full name of responsible person

Abdoreza Gholami

Position

Rezdent of Anesthsiology

Other areas of specialty/work**Street address**

Office of anesthesia , Faghi hospital , Zand Blvd

City

Shiraz

Postal code

00987117134844119

Phone

+98 71 1231 8072

Fax

+98 71 1231 8072

Email

gholamireza1256@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

shiraz University of Medical Sciences

Full name of responsible person

Abdoreza Gholami

Position

Rezdent of Anesthsiology

Other areas of specialty/work**Street address**

Office of Anesthesia, Faghi hospital , Zand Blvd

City

Shiraz

Postal code

7134844119

Phone

+98 71 1231 8072

Fax

+98 71 1231 8072

Email

www.gholami_a@internet.sums.ac.irwww.gholamireza1256@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Yadoll Zarhi

Position

Rezdent of Anesthesiology

Other areas of specialty/work**Street address**

Office of Anesthesia , Faghi Hospital , Zand Blvd

City

Shiraz

Postal code

7134844119

Phone

+98 71 1231 8072

Fax

+98 71 1231 8072

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