

# 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)

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+98 71 1233 0409

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#### 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

#### 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

#### 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

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**

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**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*