

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of intravenous prednisolone on blood pressure, pulse rate, and pain severity in patients undergoing septoplasty surgery

Protocol summary

Summary

The aim of this study is to determine the effect of intravenous prednisolone on blood pressure, pulse rate, and pain severity in patients undergoing septoplasty surgery. This study is a clinical trial, single center, with random allocation. The patients will be allocated randomly in the study groups according to encoded sheets. The population of the study are the eligible patients hospitalized in Kashani Hospital in Shahrekord. Inclusion criteria are the patients aged 20 to 50 years who are candidate for septoplasty surgery. The patients with any steroids contraindication, addicted to opioids, chronic diseases such as hypertension, and under treatment with anxiolytic medications will be excluded. Seventy-two patients will be randomly allocated in prednisolone or control (routine treatment) groups (36 in each group). In prednisolone group, 1 mg/kg prednisolone was infused before surgery, but in control group, in addition to routine anesthesia, distilled water with the same volume will be infused as placebo. All patients in both groups will receive 10 mg diazepam (orally) as premedication in the night before surgery. On the other hand, induction of anesthesia will be done using 5 mg/kg Sodium thiopental, 0.5 mg/kg Atracurium besilate, and 4 microgram/kg Fentanyl (intravenous) for patients in two study groups. In addition, twenty minutes after beginning the surgery 2 microgram/kg intravenous Fentanyl will be used. The patients' blood pressure and heart rate will be evaluated one hour before operation, ten minutes after beginning of surgery, and five minutes after entrance to recovery. In addition, after full recovery the pain severity will be measured by Visual Analogue Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503163912N7**

Registration date: **2015-06-25, 1394/04/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-25, 1394/04/04

Registrant information

Name

Kobra Nourian

Name of organization / entity

Sharekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5648

Email address

noorian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Sharekord University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-11-30, 1394/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous prednisolone on blood pressure, pulse rate, and pain severity in patients undergoing septoplasty surgery

Public title

Effect of intravenous prednisolone on blood pressure, pulse rate, and pain severity in patients undergoing septoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients aged 20 to 50 years who will candidate for septoplasty surgery. Exclusion criteria: The patients with any steroids contraindication; addicted to opioids; chronic diseases such as hypertension; and under treatment with anxiolytic medications.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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 Street

City

Shahrekord

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

1053

Health conditions studied

1

Description of health condition studied

Surgical stress

ICD-10 code

Y40-Y84

ICD-10 code description

Complications of medical and surgical care

Primary outcomes

1

Description

Blood Pressure

Timepoint

one hour before operation, ten minutes after beginning of surgery, and five minutes after entrance to recovery

Method of measurement

mmhg by sphygmomanometer

2

Description

Pulse

Timepoint

one hour before operation, ten minutes after beginning of surgery, and five minutes after entrance to recovery

Method of measurement

beat per minute/Radial artery

3

Description

Pain

Timepoint

after full recovery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

In prednisolone group, 1 mg/kg prednisolone will infused before surgery. All patients received 10 mg diazepam (orally) as premedication in the night before surgery. On the other hand, induction of anesthesia will done using 5 mg/kg Sodium thiopental, 0.5 mg/kg Atracurium besilate, and 4 microgram/kg Fentanyl (intravenous). In addition, twenty minutes after beginning the surgery 2 microgram/kg intravenous Fentanyl will used.

Category

Treatment - Drugs

2

Description

In control group, All patients received 10 mg diazepam (orally) as premedication in the night before surgery. On the other hand, induction of anesthesia will done using 5 mg/kg Sodium thiopental, 0.5 mg/kg Atracurium besilate,

and 4 microgram/kg Fentanyl (intravenous). In addition, twenty minutes after beginning the surgery 2 microgram/kg intravenous Fentanyl will used. In addition to routine anesthesia, distilled water with the same volume will infused as placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital.

Full name of responsible person

Kobra Noorian

Street address

Parastar Street, Kashani Hospital.

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Mahmmoud Mobashery

Street address

Vice chancellor for research & technology, Kashani Street.

City

Shahrekord

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

Kobra Noorian

Position

Lecturer, Nursing Dept

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