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 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 opoioids, chronic diseases such as hypertension, and under treatment with anxiolytic medications will excluded. Seventy-two patients will 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 infused as placebo. All patients in both groups will 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) for patients in two study groups. In addition, twenty minutes after beginning the surgery 2 microgram/kg intravenous Fentanyl will used. The patients' blood pressure and heart rate will 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 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

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+98 38 1333 5648

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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 opoioids; 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 sphegmomanometer

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 Haspital.
Full name of responsible person
Kobra Noorian
Street address
Parastar Street, Kashani Haspital.
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Dr. Mahmmod 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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