Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of two drug regimen: Isofluran-Remifentanil and Propofol -Remifentanil in blood pressure control and surgeon satisfaction in rhinoplasty surgery

Protocol summary

Study aim
The comparison of two drug regimen: Isofluran-Remifentanil and Propofol -Remifentanil in blood pressure control and surgeon satisfaction in rhinoplasty surgery

Design
Double Blinded Randomized Clinical Trial

Settings and conduct
Intervention group1:In the propofol and remifentanil group, patients receive propofol 50-100 µg / kg and remifentanil 0.40.1 µg / kg for maintenance of anesthesia. Intervention group2:In the isoflurane and remifentanil group, anesthesia will be maintained with a maintenance dose of isoflurane (MAC1.25%) plus remifentanil 0.40.1 µg / kg.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Patients Candidate for Rhinoplasty Surgery Age 18-50 years (ASA) I, II. Exclusion Criteria:Allergy to propofol and isoflurane or remifentanil Hypertension Cardiac Disease Anemia Liver Disease Kidney Disease CNS Disease Previous Septo-rhinoplasty COPD Disease Sever Asthma.

Intervention groups
Intervention group1:In the propofol and remifentanil group, patients receive propofol 50-100 µg / kg and remifentanil 0.40.1 µg / kg for maintenance of anesthesia. Intervention group2:In the isoflurane and remifentanil group, anesthesia will be maintained with a maintenance dose of isoflurane (MAC1.25%) plus remifentanil 0.40.1 µg / kg.

Main outcome variables
Blood Pressure ,Surgeon satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N95**
Registration date: **2020-01-14, 1398/10/24**
Registration timing: **prospective**

Last update: **2020-01-14, 1398/10/24**
Update count: **0**

Registration date
2020-01-14, 1398/10/24

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-04, 1398/11/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of two drug regimen: Isofluran-Remifentanil and Propofol -Remifentanil in blood

pressure control and surgeon satisfaction in rhinoplasty surgery

Public title
The comparison of two drug regimen: Isofluran-Remifentanil and Propofol -Remifentanil in blood pressure control and surgeon satisfaction in rhinoplasty surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients Candidate for Rhinoplasty Surgery Age 18-50 years (ASA) I, II
Exclusion criteria:
Allergy to propofol and isoflurane or remifentanil Hypertension Cardiac Disease Anemia Liver Disease Kidney Disease CNS Disease Previous Septo-rhinoplasty COPD Disease Sever Asthma
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly divided into two groups, I-R and P-R, using the randomization table from Randomization.com.
Blinding (investigator's opinion)
Double blinded
Blinding description
Anesthesia nurse who is present in the operating room will not provide any information to the recovery staff after the surgery and deliver the patient to the recovery room, while, the patient, nurse, recovery officer, and data analyst will be briefed on the study. Have been blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2019-12-14, 1398/09/23
Ethics committee reference number
IR.SUMS.MED.REC.1398.511

Health conditions studied

1

Description of health condition studied
Rhinoplasty surgery
ICD-10 code
Z41.1
ICD-10 code description
Encounter for cosmetic surgery

Primary outcomes

1

Description
Blood Pressure
Timepoint
Every 5 minutes in the operating room until the end of surgery and every 15 minutes in the recovery room until discharge
Method of measurement
Monitoring

2

Description
Surgeon satisfaction
Timepoint
End of surgery
Method of measurement
Likert scale

Secondary outcomes

1

Description
Heart Rate
Timepoint
Continuously during surgery until the end of recovery

Method of measurement
Monitoring

2

Description
Arterial Oxygen Saturation Percentage
Timepoint
Continuously during surgery until the end of recovery
Method of measurement
Pulse-oximeter

Intervention groups

1

Description
Intervention group:In the propofol and remifentanil group, patients receive propofol 50-100 µg / kg and remifentanil 0.40.1 µg / kg for maintenance of anesthesia.
Category
Prevention

2

Description
Intervention group:In the isoflurane and remifentanil group, anesthesia will be maintained with a maintenance dose of isoflurane (MAC1.25%) plus remifentanil 0.40.1 mcg / kg.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Ghadir Mother and Child Hospital
Full name of responsible person
Razieh Abbasi
Street address
Ghadir Mother And Child Hospital, Gloshan Town
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7134814336
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
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7134844119
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Email
sacrc@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Razieh Abbasi
Position
Anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Laleh Dehghanpishe

Position
Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Masihi

Position
BS in anesthesia/English Consultant

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available