Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of epinephrine injection with two different concentrations on hemodynamic changes and bleeding rate of rhinoplasty in patients under general anesthesia

Protocol summary

Study aim

Comparing hemodynamic changes and bleeding rate of rhinoplasty surgery by injecting two different concentrations of epinephrine in patients under general anesthesia can help determine the target concentration of epinephrine in rhinoplasty surgery.

Design

Randomized double-blind clinical trial with a parallel group design; case and control with 30 patient in each group

Settings and conduct

Patients undergoing elective rhinoplasty surgery at Shafa hospital in Kerman after obtaining informed consent randmally will be assigned to case and control groups and will be induced anesthesia with same drugs. The mean arterial blood pressure limit is maintained between 60-65 mm Hg with remifentanil infusion. After induction of anesthesia, in the first group (control), lidocaine 2% with adrenaline with a concentration of 1/100000 is given to the surgeon for subcutaneous injection and In the other group (case), lidocaine 2% is used in combination with adrenaline at a concentration of 1/200000.(Surgeons and anesthesiologist are unaware of the concentration of the injection material so that double-sided blinding is established.) Heart rate and blood pressure will be recorded before and after induction ofanesthesia then 1.3.5minutes after injection and every 5 minutes until end of surjury also volume of bleeding will be recorded.

Participants/Inclusion and exclusion criteria

Admission requirements: age range 16-45 years old; ASA class I ,II. Conditions prohibiting patients from entering: coagulation disorder; heart disease; hypertension; cerebrovascular disease; renal disease; drug allergies.

Intervention groups

In intervention group solution of lidocaine 2% with epinephrine 1/200000 and in control group solution of lidocaine 2% with epinephrine 1/100000 will be injected

Main outcome variables

Systolic blood pressure; diastolic blood pressure; heart rate; mean arterial blood pressure; bleeding during surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190911044743N1**
Registration date: **2020-06-14, 1399/03/25**
Registration timing: **prospective**

Last update: **2020-06-14, 1399/03/25**
Update count: **0**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name

Mahdieh Sharifzadehkermani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of epinephrine injection with two different concentrations on hemodynamic changes and bleeding rate of rhinoplasty in patients under general anesthesia

Public title
Comparison of the effect of epinephrine injection in rhinoplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People aged 16-45 years ASA I,II
Exclusion criteria:
Coagulation disorder Heart disease hypertension Cerebrovascular disease Renal disease drug Allergies
Age
From **16 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to case or control group according to restricted allocation method and random allocation rule. Allocation concealment will be with sequentially sealed envelopes and technician who is responsible for checking inclusion and exclusion criteria.
Blinding (investigator's opinion)
Double blinded
Blinding description
For all patients, the same forms are filled out by anesthesia technician in charge of the patient.The participant, the filling form technician, the surgeon and the anesthesiologist are not aware of which group the patient is in..Epinephrine with a concentration of 1/200000 or 1/1000000 is prepared by the surgeon's assistant nurse and is given to the surgeon for injection.At the end of anesthesia and after completing the form, the mark of group A or B is written on the forms by the person in charge of collecting the forms.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences
Street address
Beginning of Ibn Sina street-first Jahad boulevard-Somayeh intersection (Tahmasb Abad)-Kerman-Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2020-02-03, 1398/11/14
Ethics committee reference number
IR.KMU.REC.1398.572

Health conditions studied

1

Description of health condition studied
effect of subcutaneus epinephrine on hemodynamic changes and bleeding in rhinoplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Systolic and diastolic and mean arterial pressure
Timepoint
Before inductin by anesthesia, after intubation and then at intervals before anesthesia, after intubation, immediately before epinephrine injection, and then every minute to the third minutes after injection, and then every 5 minutes until the end of the procedure.
Method of measurement
Non-invasive automatic measurement by a monitoring device

2

Description
Heart rate
Timepoint
Before inductin by anesthesia, after intubation and then at intervals before anesthesia, after intubation,

immediately before epinephrine injection, and then every minute to the third minutes, and then every 5 minutes until the end of the procedure.

Method of measurement

EKG monitoring

3

Description

Rate of bleeding

Timepoint

End of surgury

Method of measurement

Measurment of blood in bottle of suction and number of bloody gases

Secondary outcomes

1

Description

Volume of infused propofol

Timepoint

End of surgery

Method of measurement

Volume of infusion in milliliter

2

Description

Volume of infused remifentanil

Timepoint

End of surgery

Method of measurement

Volume of infusion in milliliter

Intervention groups

1

Description

Intervention group: solution of subcutaneus epinephrine 1/200000 with lidocaine 2%

Category

Treatment - Drugs

2

Description

Control group: subcutaneus epinephrine 1/100000 with lidocaine 2%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Shafa Hospital

Full name of responsible person

Mahdieh Sharifzadeh Kermani

Street address

Shafa Medical Training Center,Kosar Boulevard,Kerman,Iran

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http://sh.kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Afzalipour Medical School,Shahid Bahonar University,end of 22 Bahman Boulevard,Kerman

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Mohadeseh Ahmadi

Position
intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared

When the data will become available and for how long
After completing the statistical design and analysis, all data are reviewed, analyzed and accessible. Start access one month after printing the results

To whom data/document is available
Data are available to academic and scientific researchers

Under which criteria data/document could be used
I don't have any specific conditions yet

From where data/document is obtainable
Refer to the person in charge of scientific accountability

What processes are involved for a request to access data/document
After e-mail and message to the person responsible for scientific response and its review, about a week later, the request will be answered

Comments