

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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 randomly 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 remifentanyl 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 of anesthesia then 1.3.5 minutes after injection and every 5 minutes until end of surgery 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)

##### Phone

+98 34 3247 4199

##### Email address

m\_sharifzadeh@kmu.ac.ir

##### 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 subcutaneous 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 induction 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 induction 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 surgery

**Method of measurement**

Measurement 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 remifentanyl

**Timepoint**

End of surgery

**Method of measurement**

Volume of infusion in milliliter

**Intervention groups****1****Description**

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

**Category**

Treatment - Drugs

**2****Description**

Control group: subcutaneous 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

**City**

Kerman

**Province**

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**Postal code**

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**Phone**

+98 34 3211 5780

**Email**

msharifzade78@gmail.com

**Web page address**

<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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**Email**

medicalschoo@kmu.ac.ir

**Web page address**

<http://sm.kmu.ac.ir>

**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

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mahdieh Sharifzadeh Kermani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mahdieh Sharifzadeh Kermani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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**