Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison of the results and complications caused by the injection of 1/1,000,000, 1/500,000 and 1/200,000 dilutions of epinephrine in normal saline in the surgical field, on patients who are candidates for head and neck surgery, a clinical trial

Protocol summary

Study aim

Determining the optimal dilution of epinephrine, which while reducing the amount of bleeding in the surgical field, has the least cardiovascular complications, including changes in blood pressure and cardiac arrhythmias, and in addition, we see the lowest amount of flap necrosis

Design

Three-group randomized clinical trial with parallel and double-blind groups. Randomized with random blocks, phase 2-3 on 80 patients.

Settings and conduct

This study was performed in Kosar Hospital of Semnan province on patients who are candidates for head and neck surgeries by diluting epinephrine vials of 1 in 10,000 to the three dilutions mentioned above as topical injection during surgery with blue needle syringes and parallel to it. Bleeding is monitored in the operation field and changes in patients' heart rate and rhythm and blood pressure are performed The patient does not know which group he is placed in, and the care personnel will not know how the patients are assigned to the groups and the results of the intervention. The study information is not obvious to the statistician and will be identified by the letters A, B, C. This study will be double-blind .

Participants/Inclusion and exclusion criteria

Patients aged 16_70 non hypertensive . candidate for head and neck surguries

Intervention groups

Three groups: in the first group (A), for surgical injection of epinephrine with a dilution of 1 in 200,000 and in the second group (B) of epinephrine with a dilution of 1 in 500,000 and in the third group (C) of epinephrine with a dilution of 1 At 1,000,000

Main outcome variables

Number of epinephrine injections required per group; bleeding amount in field ;blood pressure changes during surgury; arythmies during surgury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220524054981N1**
Registration date: **2022-07-25, 1401/05/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-25, 1401/05/03**
Update count: **0**

Registration date

2022-07-25, 1401/05/03

Registrant information

Name

pantea zahedinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3323 2621

Email address

panteaazahedinia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the results and complications caused by the injection of 1/1,000,000, 1/500,000 and 1/200,000 dilutions of epinephrine in normal saline in the surgical field, on patients who are candidates for head and neck surgery, a clinical trial

Public title

Evaluation of the effect of epinephrine doses in head and neck surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patient (non hypertensive) that are candidate for head and neck surgeries aged 16_70

Exclusion criteria:

Age < 16 and age > 70 Hypertention

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples (into three groups) is done randomly using the Block Randomization method with 9 blocks of 9 assigned to three groups. In this method, A represents group one (injection of epinephrine during surgery with a dilution of 1 in 200,000), B represents group two (injection of epinephrine during surgery with a dilution of 1 in 500,000), and C represents group three (injection of epinephrine during surgery with a dilution of 1 in 500,000). The dilution will be one in 1,000,000). In this way, the sequence of interventions A, B, and C in the form of blocks from number 1 to 10 is determined by the plan's epidemiologist consultant and given to the executive supervisor of the plan, and the researcher receives assignments from the executive supervisor to assign each eligible person. slow First, the executive supervisor selects the block using random numbers (the assignment list will be prepared with the help of the epidemiologist consultant and before starting the work based on the random numbers created through Excel software (between 0 and 1)) and then the people Qualified persons are assigned to one of the three groups A, B or C according to the pre-determined order by the epidemiologist consultant. It should be mentioned that if a block is selected based on random numbers and all 9 sequences have already been filled in it, another random number will be selected for that individual. More about this source textSource text required for additional translation information Send feedback Side panels

Blinding (investigator's opinion)

Double blinded

Blinding description

The sample selection process in the groups will be done by the researcher and the day before the operation. Therefore, the patient does not know which group he is placed in, and the care personnel will not know how the patients are assigned to the groups and the results of the intervention. The study information is not obvious to the statistician and will be identified by letters A, B, C. This study will be double-blind (surgeon and statistician will be unaware of the patient group). The day before the operation, the researcher will obtain informed and written consent from the people to participate in the study if they meet the criteria for entering the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of semnan university of medical sciences

Street address

Golestan

City

Semnan

Province

Semnan

Postal code

99951-35198

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.SEMUMS.REC.1401.077

Health conditions studied

1

Description of health condition studied

Optimal and optimal dilution of epinephrine, which, while reducing the amount of bleeding in the surgical field, has the least cardiovascular complications, including changes

in blood pressure and cardiac arrhythmias

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in blood pressure

Timepoint

During the surgery

Method of measurement

Monitoring

2

Description

Cardiac arrhythmias

Timepoint

During the surgery

Method of measurement

Monitoring

3

Description

The amount of bleeding during the operation

Timepoint

during the surgury

Method of measurement

Check list

4

Description

Number of times required for topical injection of epinephrine in the operation field

Timepoint

During the surgery

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receive a dilution of 1 in 200,000 (Epinaline brand from Iran Hormon Company) to dilute epinephrine: First, we mix 1 cc of a 1/10000 vial of epinephrine with 9 cc of normal saline in a 10 cc syringe. The obtained dilution will be 1/100,000. Now, to prepare the 1/200,000 dilution, mix 1 cc of the 1/100,000 preparation with 1 cc of normal saline in a 2 cc syringe. How to administer epinephrine: in the surgical field using Injections are made from 2, 5, and 10 cc syringes with fine needle heads (blue color). In relation to the volume of diluted epinephrine in the surgical field: the injection volume varies between 50 and 200 cc, which depends on the type. It works, for example, in rhinoplasty, this amount is 50 cc, but in cranioplasty, it can be up to 100 cc.

Category

Treatment - Surgery

2

Description

Intervention group: Receive a dilution of 1 in 500,000 (Epinaline brand from Iran Hormon Company) to dilute epinephrine: First, we mix 1 cc of a 1/10000 vial of epinephrine with 9 cc of normal saline in a 10 cc syringe. The obtained dilution will be 1/100000. To prepare a dilution of 1/500000. Mix 1 cc of the prepared 1/100000 solution with 4 cc of normal saline in a 5 cc syringe. How to administer epinephrine: in the surgical field using 2, 5, and 10 cc syringes with fine needle heads (blue color) injection is performed in relation to the volume of diluted epinephrine in the surgical field: the injection volume varies between 50 and 200 cc, which depends on the type of operation, for example, in rhinoplasty, this amount is 50 cc But in cranioplasty, it can be up to 100 cc

Category

Treatment - Surgery

3

Description

Intervention group: Receive a dilution of 1 in 1000,000 (Epinaline brand from Iran Hormon Company) to dilute epinephrine: First, we mix 1 cc of a 1/10000 vial of epinephrine with 9 cc of normal saline in a 10 cc syringe. The obtained dilution will be 1/100000. To prepare a dilution of 1/1000000. Mix 1 cc of the prepared 1/100,000 solution with 9 cc of normal saline in a 10 cc syringe. How to administer epinephrine: in the surgical field using 2, 5, and 10 cc syringes with fine needle heads (blue The injection is performed in relation to the volume of diluted epinephrine in the surgical field: the injection volume varies between 50 and 200 cc, which depends on the type of operation, for example, in rhinoplasty, this amount is 50 cc, but In cranioplasty, up to 100 cc is possible

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Pantea Zahedinia

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
pantea zahedinia
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5 km of Damghan road
City
Semnan
Province
Semnan
Postal code
35147-99442
Phone
+98 23 3344 1022
Email
info@semums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Pantea zahedinia
Position
Medical intern
Latest degree
A Level or less
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Position
Medical intern
Latest degree
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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 potentially be shared after de-identifying subjects. Main results can also be shared after the study is completed.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

If researchers working in academic and scientific institutions submit a request to use the data in future related research, the data will be usable.

From where data/document is obtainable

through the e-mail address of the researcher : pantea zahedinia : panteaazahedinia @gmail.com

What processes are involved for a request to access data/document

6 months after the results are published, it is possible to receive the mentioned documents through the researcher's email address, which is provided to the applicants.

Comments