

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the combined effect of dexmedetomidine and tranexamic acid on bleeding and surgeon satisfaction in nasal surgery.

Protocol summary

Study aim

Reducing bleeding in nasal surgery and increasing surgeon satisfaction

Design

The current clinical trial without a control group, with parallel groups, double-blind, is on 105 patients, which is done by the block method and using Excel.

Settings and conduct

This study is carried out in the operating room of Ba'ath Hospital in Hamedan. In this study, a combination of dexmethomidine and tranexamic acid is injected to patients to prevent nose surgery bleeding. In this study, in order to make the study double-blind, the drugs are prepared in advance by the researcher and provided to the clinical caregiver. And the evaluator is not aware of the patient classification.

Participants/Inclusion and exclusion criteria

Candidates for rhinoplasty surgery whose hemoglobin is more than 10 and whose age is more than 18 years old can enter the study. Patients with a history of heart disease, seizures and chronic hypertension cannot participate in this study.

Intervention groups

Patients who are candidates for rhinoplasty surgery receive a group of tranexamic acid drugs to prevent bleeding during surgery. The second group receives the drug dexmethomidine to prevent surgical bleeding, and the third group receives the combination of two drugs, tranexamic acid and dexmethomidine.

Main outcome variables

In this study, bleeding during surgery and surgeon satisfaction during surgery are examined

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230816059159N1**

Registration date: **2023-10-01, 1402/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-01, 1402/07/09**

Update count: **0**

Registration date

2023-10-01, 1402/07/09

Registrant information

Name

Ibrahim Karilm

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1014

Email address

ebrahimhadad5@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the combined effect of dexmedetomidine and tranexamic acid on bleeding and surgeon satisfaction in nasal surgery.

Public title

combined effect of dexmedetomidine and tranexamic

acid in nasal surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is a candidate for nasal surgery The patient must be at least 18 years old The patient has informed consent

Exclusion criteria:

The patient has a history of heart disease The patient has a history of seizures The patient has a history of hypertension

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The people under study will be assigned to three intervention groups using the random number generation software. In this way, first, a random table is designed using Microsoft Excel software for the number of samples (102 samples). Numbers 1 to 34 are assigned to the tranexamic acid group, numbers 35 to 68 to the dexmethomedin group, and numbers 69 to 102 to the combined group. Patients are divided into groups in the order they enter the study using a random table. study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications are prepared in uniform syringes by the researcher and provided to the clinical caregiver. The clinical caregiver does not know which patient is receiving which drug. The evaluator also does not know which insurance company received which medicine.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical

Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh St, Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517838765

Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.UMSHA.REC.1402.383

Health conditions studied

1

Description of health condition studied

Bleeding rate in nasal candidate patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

surgery bleeding

Timepoint

Bleeding measurement time: before drug injection, after drug injection every 15 minutes until the end of surgery

Method of measurement

Volume of blood suctioned in cubic centimeters

2

Description

surgeon satisfaction

Timepoint

before drug injection, after drug injection every 15 minutes until the end of surgery

Method of measurement

The surgeon's satisfaction is evaluated based on a four-point classification

Secondary outcomes

1

Description

The patient's blood pressure

Timepoint

Every 15 minutes after drug injection until the end of surgery

Method of measurement

sphygmomanometer

Intervention groups

1

Description

Combined injection of dexmethomadine (Made by Arang drug therapy Pharmaceutical Company) and ternaxamic acid (Made by Caspian Pharmaceutical Company) in the prevention of bleeding in patients who are candidates for nose surgery. after the start of general anesthesia, tranexamic acid will prescribe at a dose of 10 mg per kilogram of body weight at a rate of 100 mg per minute. prevention of bleeding in patients who are candidates for nose surgery, dexmedetomidine will prescribe 0.1 micrograms per kilogram of body weight within 10 minutes and then 0.5 micrograms per kilogram of body weight is prescribed within an hour. These drugs are prescribed intravenously.

Category

Prevention

2

Description

Injection of dexmedetomidine (Made by Arang drug therapy Pharmaceutical Company) in the prevention of bleeding in patients who are candidates for nose surgery, dexmedetomidine will prescribe 0.1 micrograms per kilogram of body weight within 10 minutes and then 0.5 micrograms per kilogram of body weight is prescribed within an hour. and during the surgery, this drug is injected intravenously. the patient's bleeding rate and the surgeon's satisfaction are checked.

Category

Prevention

3

Description

Injection of ternaxamic acid (Made by Caspian Pharmaceutical Company) in the prevention of bleeding in patients who are candidates for nose surgery. At the beginning of the surgery, this drug is injected intravenously to the patient in one step, after the start of general anesthesia, tranexamic acid will prescribe at a dose of 10 mg per kilogram of body weight at a rate of 100 mg per minute. and during the surgery, the patient's bleeding rate and the surgeon's satisfaction are checked.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Besat Hospital

Full name of responsible person

Dr. Behrooz Phankarei

Street address

Besat Hospital, Shahid Motahari Blvd, Resalat Square,

Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3264 0020

Email

ebrahimhadad5@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farzaneh Aslani

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh St

City

Hamedan

Province

East Azarbaijan

Postal code

6517838756

Phone

+98 81 3838 1014

Email

webda@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

40

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

Hamedan University of Medical Sciences

Full name of responsible person

Behroz Karkhanei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Fahmida St, Hamadan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838667

Phone

008138381014

Email

bk13472000@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Behroz Karkhanei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Fahmida St, Hamadan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838765

Phone

+98 81 3838 1014

Email

bk13472000@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Ebrahim Karim

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Shahid Fahmideh, Hamadan University of Medical

Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838765

Phone

+98 81 3838 1014

Fax**Email**

ebrahimhadad5@gmail.com

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

This information is made available after de-identifying individuals and includes information that reports the main outcomes of the plan.

When the data will become available and for how long

Access starts from 2031

To whom data/document is available

The access of anesthesia department instructors is allowed

Under which criteria data/document could be used

The use of data in the way of patient control is unimpeded, its use in the context of review studies is allowed. The data can be used in review studies. In this field, university professors and educational researchers can receive documents by presenting them.

From where data/document is obtainable

You can access the data by referring to Hamadan University of Medical Sciences, Faculty of Paramedicine, Department of Intelligence, Room 4 or by sending an email to the mentioned address.
bk13472000@yahoo.com

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

By sending an email to Behrouz karkhanei and stating the reason for the request, he can use or access the data with an acceptable and effective reason for the education and care of patients.

Comments