

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of tranexamic acid and remifentanil on intraoperative hemorrhage in dacryocystorhinostomy and comparing with control group

Protocol summary

Study aim

Comparison of the effect of tranexamic acid and remifentanil on intraoperative hemorrhage in dacryocystorhinostomy and comparing with control group

Design

This study is a double-blind randomized clinical trial study with parallel groups. 165 patients undergoing dacryocystorhinostomy surgery will be divided into three groups with using Random Allocation Software. The groups were included intervention group 1 (receiving bolus of tranexamic acid 15 mg / kg in a 15-minute period with 500 ml of normal saline), intervention group 2 (receiving remifentanil infusion of 0.1 to 0.3 µg / kg / min until the end of surgery), group 3 (placebo).

Settings and conduct

This study was carried out in Feyz hospital in Isfahan during 2018 to 2020. A total of 165 patients undergoing DCR surgery are enrolled in the study according to inclusion and exclusion criteria and are divided into three groups of tranexamic acid and remifentanil and control by random allocation software. Patients, drug prescriber, data collector, and data analyzer were not aware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for classic dacryocystorhinostomy surgery, age range between 18 and 75 years, no sensitivity to drugs, no coagulation problems, no addiction, no chronic underlying disease
Exclusion criteria: Changing the anesthesia procedure

Intervention groups

Intervention group 1: receiving bolus of tranexamic acid 15 mg / kg in a 15-minute period with 500 ml of normal saline, intervention group 2: receiving remifentanil infusion of 0.1 to 0.3 µg / kg / min until the end of surgery, group 3: placebo.

Main outcome variables

Intraoperative bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N42**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of tranexamic acid and remifentanyl on intraoperative hemorrhage in dacryocystorhinostomy and comparing with control group

Public title
Effect of tranexamic acid and remifentanyl on intraoperative hemorrhage in dacryocystorhinostomy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidate for classic dacryocystorhinostomy surgery Age range between 18 and 75 years No sensitivity to drugs No coagulation problems No addiction No chronic underlying disease
Exclusion criteria:
Changing the anesthesia procedure

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **165**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 165 patients undergoing DCR surgery are enrolled in the study according to inclusion and exclusion criteria and are divided into three groups of tranexamic acid and remifentanyl and control by random allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are anesthetized and have no knowledge of the treatment group, and the drug is injected by an anesthesiologist who is blinded of the treatment and is not involved in the measurements. Measurements are performed by the project manager who is aware of the grouping. The information is coded into the software and the analyzer is unaware of the group assignment. After the design and analysis of the data, the codes are opened.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-07-15, 1398/04/24

Ethics committee reference number

IR.MUI.MED.REC.1398.197

Health conditions studied

1

Description of health condition studied

dacryocystorhinostomy

ICD-10 code

H04.549

ICD-10 code description

Stenosis of unspecified lacrimal canaliculi

Primary outcomes

1

Description

Intraoperative bleeding

Timepoint

From the beginning of the operation to the end of the operation

Method of measurement

The volume of blood suctioned per ml

Secondary outcomes

1

Description

Hemodynamic Disorder

Timepoint

Every 15 minutes during operation and recovery

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Intervention group: receiving bolus of tranexamic acid 15 mg / kg in a 15-minute period with 500 ml of normal saline

Category

Prevention

2

Description

Intervention group: receiving remifentanil infusion of 0.1 to 0.3 µg / kg / min until the end of surgery

Category

Prevention

3

Description

Control group: receiving placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Kamran Montazeri

Street address

Modarres Street

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8174673461

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montazeri@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayesh Haghjoo

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Kamran Montazeri

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

Professor

Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ali Mehrabi
Position
Statistical consultant
Latest degree
Master
Other areas of specialty/work
Epidemiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Information belongs to government agency
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Because the information belongs to a government agency, it cannot be shared.
When the data will become available and for how long
Any time
To whom data/document is available
Any person
Under which criteria data/document could be used
Under any circumstances
From where data/document is obtainable
Any person, any time
What processes are involved for a request to access data/document
Any procedure
Comments