Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 31 3629 1510

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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 remifentanil on intraoperative hemorrhage in dacryocystorhinostomy and comparing with control group

Public title

Effect of tranexamic acid and remifentanil 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 remifentanil 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

Isfehan

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
City
Isfahan
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Isfehan
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8174673461
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayesh Haghjoo
Street address
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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
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Person responsible for updating data

Contact
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Esfahan University of Medical Sciences
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Ali Mehrabi
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Statistical consultant
Latest degree
Master
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al.mehrabi@gmail.com

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