Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

A comparative study on the effect of two compounds of Propofol-Remifentanil and Propofol-Hydralazine on volume of blood loss during dacryocystorhinostomy with general anesthesia

Protocol summary

Study aim

Determination and comparison of the effect of two compounds of propofol-remifentanil and propofol-hydralazine on bleeding volume during dacryocystorhinostomy surgery under general anesthesia

Design

A three phase clinical trial with two intervention groups, in parallel, double-blind, randomized with simple method, with sample size of 80

Settings and conduct

This study will be conducted in Isfahan Feiz hospital in 1389-1388. Patients are divided into two groups.At first, 5 cc/kg of crystalloid fluid is injected and 100% oxygen is given by the mask in the first 3 minutes. Anesthesia is induced by injection of 2 µg/kg fentanyl, 2 mg/kg propofol and 0.5 mg/kg atracurium, and intubation is done.In both groups, propofol infusion will be started at a dose of 12 mg/kg/hr (200 µg/kg/min) and then reduced to 6-10 mg / kg / hr (150-50 µg/kg/min).In group A 40 cc propofol plus 0.15 µg/kg remifentanil and in group B the same amount of propofol with 20 mg hydralazine is prepared and the infusion would start at a dose of 50-150 µg/kg/min.At last the volume of blood collected in the suction is recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA I, II patients who are candidates for DCR surgery Age range 18 to 80 years No contraindication for Hydralazine, Remifentanil and Propofol Consent to participate in the study Exclusion criteria: Known allergies to medicines Having heart disease Having diabetes mellitus Obvious anemia Having hemoglobinopathy Having polycythemia Having liver disease Ischemic cerebrovascular disease Having respiratory failure Systemic hypertension Any complication that may alter the anesthesia program Occurrence of complications such as heart block, etc. that prohibit or restrict the continuation of the intervention

Intervention groups

1

Main outcome variables

Bleeding volume, Blood pressure, Heart rate,recovery time, Extubation time, Surgeon satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N30**
Registration date: **2020-02-05, 1398/11/16**
Registration timing: **prospective**

Last update: **2020-02-05, 1398/11/16**
Update count: **0**

Registration date

2020-02-05, 1398/11/16

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of two compounds of Propofol-Remifentanil and Propofol-Hydralazine on volume of blood loss during dacryocystorhinostomy with general anesthesia

Public title

Comparison of the effect of two compounds of Propofol-Remifentanil and Propofol-Hydralazine on volume of blood loss during dacryocystorhinostomy with general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I, II patients who are candidates for DCR surgery Age range 18 to 80 years No contraindication for Hydralazine, Remifentanil and Propofol Consent to participate in the study

Exclusion criteria:

Known allergies to medicines Having heart disease Having diabetes mellitus Obvious anemia Having hemoglobinopathy Having polycythemia Having liver disease Ischemic cerebrovascular disease Having respiratory failure Systemic hypertension Any complication that may alter the anesthesia program Occurrence of complications such as heart block, etc. that prohibit or restrict the continuation of the intervention

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients included in the study are randomly assigned into two groups using Random allocation computer software with the simple method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because the patient is unaware of the type of drug used and the anesthesiologist is unaware of the type of intervention, this is a double-blind study.

Placebo

Not 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

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City

Isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2019-07-31, 1398/05/09

Ethics committee reference number

IR.MUI.MED.REC.1398.528

Health conditions studied

1

Description of health condition studied

Blood loss during surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bleeding volume

Timepoint

After intervention

Method of measurement

Suction

Secondary outcomes

1

Description

Blood pressure

Timepoint
Before and after intervention
Method of measurement
Non-invasive automatic barometer

2

Description
Heart rate
Timepoint
Before and after intervention
Method of measurement
Pulse Oximeter

3

Description
Length of staying in recovery
Timepoint
After intervention
Method of measurement
Modified Aldrete Score

4

Description
Surgeon satisfaction
Timepoint
After intervention
Method of measurement
likert scale

Intervention groups

1

Description
First intervention group:In group A in a 50 cc syringe 40 cc propofol with 0.15 µg / kg remifentanil is prepared and eventually the infusion at a dose of 50-150 µg/kg/min will be started. At the end of surgery, blood volume in the suction is observed and recorded.
Category
Treatment - Drugs

2

Description
Second intervention group:In group B, 40 cc of propofol with 20 mg of hydralazine will be prepared and the infusion will eventually start at a dose of 50-150 µg / kg / min. At the end of surgery, the volume of blood collected in the suction is observed and recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Hamidreza Shetabi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Hamidreza Shetabi
Position
Professor of Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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