

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

Name

Sadra Ansaripour

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

Isfahan

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 remifentanyl 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

Isfahan Province, Isfahan, Modarres St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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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