

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative Study on the Effect of two Labetalol-Nitroglycerine Combinations with Labetalol-Hydralazine on volume blood loss During Ducricysturinostomy with Local Anesthesia

Protocol summary

Study aim

Evaluation of the effect of combination of two drug combinations of labetalol-tri-nitroglycerin with labetalol-hydralazine on bleeding volume during dacryocystorhinostomy with local anesthesia

Design

The present study is a double-blind clinical trial (the patient and the registrant are unaware of the type of drug used) that will be performed at Feyz Isfahan Medical Center in 1397-98. Patients undergoing DCR surgery They are not contraindicated with hydralazine, tri-nitroglycerin and labetalol and are in the age range of 18 to 80 years.

Settings and conduct

at Feyz Isfahan Medical Center in 1397-98

Participants/Inclusion and exclusion criteria

Patients undergoing DCR surgery who are not contraindicated with hydralazine, tri-nitroglycerin and labetalol and are in the age range of 18 to 80 years 2. Patient consent for inclusion in the study Patient Exclusion Criteria: 1. A known allergy to medicines 2. Heart disease 3. Diabetes mellitus, prominent anemia 4- Hemoglobinopathy 5. Polycythemia 6. Liver disease 7- Cerebrovascular ischemic disease 8- Respiratory failure 9. Systemic hypertension

Intervention groups

Group A recipient of labetalol-tri-nitroglycerin and group B recipient of labetalol-hydralazine

Main outcome variables

Determination and Comparison of Mean Bleeding Volume in Labetalol-Trititroglycerin Consumption Group with Labetalol-Hydralazine Consumption Group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044020N1**

Registration date: **2019-12-29, 1398/10/08**

Registration timing: **retrospective**

Last update: **2019-12-29, 1398/10/08**

Update count: **0**

Registration date

2019-12-29, 1398/10/08

Registrant information

Name

Elnaz Marzbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4253 5407

Email address

dr.marzbani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study on the Effect of two Labetalol-Nitroglycerine Combinations with Labetalol-Hydralazine

on volume blood loss During Dacryocystorhinostomy with Local Anesthesia

Public title

Comparative Study on the Effect of two Labetalol-Nitroglycerine Combinations with Labetalol-Hydralazine on volume blood loss During Dacryocystorhinostomy with Local Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing DCR surgery who are not contraindicated with hydralazine, tri-nitroglycerin, and labetalol, aged 18 to 80 years Patient Satisfaction for Inclusion

Exclusion criteria:

Known allergies to medicines Heart disease Diabetes mellitus, obvious anemia Hemoglobinopathy Polycythemia Liver disease Cerebrovascular ischemic disease

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization Unit: Individual Randomization Tool:
Random Number Table

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness is that after giving the patient complete information. If there are no criteria for exclusion, the patient will be entered into the study after obtaining informed consent. The patient is not informed about the type of medication used during the study. They also do not know the type of medication used when assistants and health care providers gather information

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

Daneshgah street, Isfahan University of Medical Sciences

City

Esfahan

Province

Isfahan

Postal code

81746443446

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.MUI.MED.REC.1398.004

Health conditions studied

1

Description of health condition studied

stenosis and insufficiency of lacrimal passages

ICD-10 code

H04.5

ICD-10 code description

stenosis and insufficiency of lacrimal passages

Primary outcomes

1

Description

Determination of the mean volume of bleeding in Dacryocystorhinostomy to CC

Timepoint

The volume of blood collected in the suction device at the end of surgery

Method of measurement

Blood collected in suction to cc

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: After the patient is placed on the baseline monitoring bed including systolic blood pressure, diastolic blood pressure, heart rate and respiratory rate. Then, local anesthesia will be performed by the surgeon using 8 cc lidocaine 2% in both groups. Both groups are given a bolus of labetalol dose of 20 mg within 2 minutes. Doses and rate of intravenous injection are selected based on the policy for hypertension crisis. Then the infusion of labetalol at a rate of 0.5 - 1 mg / min and

the maximum dose received will be 300 mg. Group A patients start intravenous infusion of Tri-nitroglycerin 15 - 20 mcg / min from the lower limit and increase every 5 minutes if necessary to reach target MAP.

Category

Treatment - Drugs

2**Description**

Intervention group 1: After the patient is placed on the baseline monitoring bed including systolic blood pressure, diastolic blood pressure, heart rate and respiratory rate. Then, local anesthesia will be performed by the surgeon using 8 cc lidocaine 2% in both groups. Both groups are given a bolus of 20 mg within 2 minutes. Doses and rate of intravenous injection are selected based on the policy for hypertension crisis. Then the infusion of labetalol at a rate of 0.5 - 1 mg / min and the maximum dose received will be 300 mg. In group B, hydralazine is given 0.5 - 1 mg / min intravenous infusion. The level starts from the lower limit if necessary, increasing every 5 minutes to achieve target MAP.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Feyz Isfahan Medical Center

Full name of responsible person

Dr Ali Salehi

Street address

Modarres street

City

Esfahan

Province

Isfahan

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Email

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Web page address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Syed Morteza Heydari

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

Dr Syed Morteza Heydari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Daneshgah street, Isfahan University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Syed Morteza Heydari

Position

Profossor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Confidentiality of information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data and documentation will be available except personal patient information

When the data will become available and for how long

unlimited

To whom data/document is available

unlimited

Under which criteria data/document could be used

For scientific and expansive use of research

From where data/document is obtainable

Isfahan University of Medical Sciences Library

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

Isfahan University of Medical Sciences Library

Comments

No additional explanation