Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The evaluation of the effect of different doses of labetalol on bleeding volume during and after dacryocystorhinostomy surgery

Protocol summary

Study aim
Determining and comparing the effect of different doses of labetalol on bleeding volume during and after dacryocystorhinostomy surgery

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 84 patients

Settings and conduct
In this randomized triple-blind clinical trial, 84 eligible patients referred to Feiz Hospital in Isfahan will be included in the study and randomly divided into three groups. Patients in the first group labetalol at a dose of 0.2 mg/kg, and in the second group labetalol at a dose of 0.4 mg/kg, and in the control group placebo will be injected. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention and the triple-blind conditions will be established. Then the bleeding volume and hemodynamic parameters of the patients will be evaluated and compared between the three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include candidate for elective dacryocystorhinostomy surgery, age range 20 to 64 years, and having the I and II classification of the American Society of Anesthesiologists. Exclusion criteria include a history of blood diseases, coagulopathy, allergy to labetalol, any uncontrolled systemic disease, recent use of anticoagulants, and a history of malignant hyperthermia.

Intervention groups
First intervention group: In this group, labetalol at a dose of 0.2 mg/kg will be administered as an infusion 5 minutes after induction of anesthesia. The second intervention group: In this group, labetalol at a dose of 0.4 mg/kg will be administered as an infusion 5 minutes after induction of anesthesia. Control group: In this group, the placebo will be administered as an infusion 5 minutes after induction of anesthesia.

Main outcome variables
Bleeding volume; Blood pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N43**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **prospective**

Last update: **2021-10-02, 1400/07/10**
Update count: **0**

Registration date
2021-10-02, 1400/07/10

Registrant information
Name
Asieh Maghami Mehr
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 0000 0000
Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation of the effect of different doses of labetalol on bleeding volume during and after dacryocystorhinostomy surgery

Public title
The effect of different doses of labetalol on bleeding volume during and after dacryocystorhinostomy surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for elective dacryocystorhinostomy surgery Age range 20 to 64 years Class I and II classification of the American Society of Anesthesiologists
Exclusion criteria:
History of blood diseases, coagulopathy Allergy to labetalol Existence of any uncontrolled systemic disease Recent use of anticoagulants History of malignant hyperthermia
Age
From **20 years** old to **64 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 84 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into three groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the three study groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to achieve the triple-blind study, different doses of labetalol and placebo (without labetalol) will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B, and C. And is given daily to the anesthesiologist (researcher). Therefore, the patient, Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
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
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2021-04-28, 1400/02/08
Ethics committee reference number
IR.MUI.MED.REC.1400.076

Health conditions studied

1

Description of health condition studied
Dacryocystorhinostomy
ICD-10 code
H04.0
ICD-10 code description
Dacryoadenitis

Primary outcomes

1

Description
Bleeding volume
Timepoint
During surgery and in recovery
Method of measurement
Measure the amount of blood in the suction

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Immediately before surgery and then every 15 minutes during surgery and then every 15 minutes to an hour in

recovery

Method of measurement

Monitoring device

2

Description

Diastolic blood pressure

Timepoint

Immediately before surgery and then every 15 minutes during surgery and then every 15 minutes to an hour in recovery

Method of measurement

Monitoring device

3

Description

Mean Arterial Pressure

Timepoint

Immediately before surgery and then every 15 minutes during surgery and then every 15 minutes to an hour in recovery

Method of measurement

Monitoring device

4

Description

Hear rate

Timepoint

Immediately before surgery and then every 15 minutes during surgery and then every 15 minutes to an hour in recovery

Method of measurement

Monitoring device

Intervention groups

1

Description

First intervention group: In this group, labetalol at a dose of 0.2 mg / kg will be administered as an infusion 5 minutes after induction of anesthesia.

Category

Treatment - Drugs

2

Description

The second intervention group: In this group, labetalol at a dose of 0.4 mg / kg will be administered as an infusion 5 minutes after induction of anesthesia.

Category

Treatment - Drugs

3

Description

Control group: In this group, placebo will be administered as an infusion 5 minutes after induction of anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz Hospital

Full name of responsible person

Daroush Moradi Farsani

Street address

Ayatollah Modarres Street, Ghods Square, Isfahan.

City

Isfahan

Province

Isfehan

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Phone

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dmoradi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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
Daroush Moradi Farsani
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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
There is no further information
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
No - There is not 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