Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of phenylephrine drops on the blood loss during and after reconstructive surgery of cleft palate in children

Protocol summary

Study aim
Determining the effect of nasal phenylephrine drops on the amount of bleeding in cleft palate surgery

Design
A clinical trial with the control group, with parallel groups, double-blind, randomized, on 36 patients. Randomization with the table of random numbers.

Settings and conduct
Sampling is performed in Hazrat Fatemeh Hospital of Iran University of Medical Sciences. Patients are all placed under general anesthesia, then endotracheal intubation is performed and isoflurane and N2O are used to maintain anesthesia. Patients are operated on by a surgeon at the same time interval. In the intervention group, two drops of phenylephrine 0.25% are poured into each nose, and in the control group, the same amount of placebo is used. Then the amount of bleeding is done by calculating the volume of blood inside the suction and the number of blood gases, and the surgeon's satisfaction in terms of the quality of the operation site is assessed using the Likert and Boozart checklists. All necessary measures are taken to manage complications.

Participants/Inclusion and exclusion criteria
Children 6 months to 2 years old who are candidates for cleft palate surgery

Intervention groups
After induction of anesthesia, 2 drops of phenylephrine 0.25% In the intervention group and 2 drops of placebo in the control group are poured into each nostril.

Main outcome variables
Calculation of blood volume in suction, number of blood gases and their weight, surgeon's satisfaction in terms of quality of operation site and amount of bleeding

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170301032837N4**
Registration date: **2021-05-12, 1400/02/22**
Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**
Update count: **0**

Registration date
2021-05-12, 1400/02/22

Registrant information
Name
Behrooz Zaman
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-05-22, 1400/03/01
Expected recruitment end date
2021-09-22, 1400/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of phenylephrine drops on the blood loss during and after reconstructive surgery of cleft palate in children

Public title

The effect of nasal phenylephrine drops on palatoplasty blood loss

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for cleft palate surgery Age between 6 months to two years Weight between 7 to 21 kg

Exclusion criteria:
Anemia Cardiovascular disorders Coagulopathies Coagulopathies in Family Any congenital and genetic disorders

Age
From **6 months** old to **2 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple, individual randomization using a table of random numbers, so that the first patient is placed in one of the two groups by lottery. The next patient will be placed in one of the two groups using a table of random numbers based on even and odd numbers, and this sequence will continue. The intervening researcher and evaluator are unaware of the random sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
The person who drops, the person who evaluates the bleeding, and the surgeon have no information. To prepare the placebo, empty a container of phenylephrine drops and fill it with distilled water instead. Make it in a form similar to phenylephrine drops and name solutions 1 and 2 and give it to the person who drops without knowing the type of solution.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
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1449614535

Approval date
2020-10-20, 1399/07/29

Ethics committee reference number
IR.IUMS.FMD.REC.1399.462

Health conditions studied

1

Description of health condition studied
Cleft palate

ICD-10 code
Q35

ICD-10 code description
Cleft palate

Primary outcomes

1

Description
Intraoperative blood loss

Timepoint
During the operation and the end of the operation

Method of measurement
Counting and weighing blood gases, blood in suctioning bottle

Secondary outcomes

1

Description
Surgeon satisfaction with the operation field

Timepoint
At the end of surgery

Method of measurement
Likert scale, Boozart scale

Intervention groups

1

Description
Intervention group:After induction of anesthesia and before the preparation of the operation, two drops of phenylephrine 0.25% are instilled in each nostril.

Category
Prevention

2

Description
Control group: After induction of anesthesia and before preparation, two drops of distilled water are instilled into each nostril from a container similar to a phenylephrine container.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat-e Fatemeh Hospital

Full name of responsible person
Dr. Noor ahmad Latifi

Street address
21st. street. Assadabadi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Seyyed Abbas Motevalian

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Behrooz Zaman

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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