

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8871 7272

###### Email address

zaman.b@iums.ac.ir

##### 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

Tehran

## Postal code

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.

**City**

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**Province**

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crtfatima@iums.ac.ir

**Web page address**

<https://crtfatima.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Seyyed Abbas Motevalian

**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**

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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Hazrat-e Fatemeh Hospital, 21st Street, Asadabadi  
Ave.

**City**

Tehran

## 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