

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparision between of Ropivacaine and Lidocain with Epinephrin in patient undergoing cleft palate repair

#### Protocol summary

##### Study aim

Comparision between of Ropivacaine and Lidocain with Epinephrin in patient undergoing cleft palate repair

##### Design

Clinical trial without control group, with parallel groups, one-way blind, randomized, phase 2 on 40 patients. Random allocation was used for randomization.

##### Settings and conduct

Intervention group 1: Lidocaine 2 mg per kg body weight with epinephrine 1/80000, Intervention group 2: ropevacaine 2 mg per kg body weight of solution o.5% is injected locally at the incision site by the surgical service. This single-blind study, which is used in patients before surgery, patients do not know the type of drug used

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for cleft palate surgery  
Exclusion criteria: Allergy to local anesthetics; Bleeding disorders; Cardiovascular disorders; Brain disorders

##### Intervention groups

Intervention group 1: Lidocaine 2 mg per kg body weight with epinephrine 1/80000 Intervention group 2: ropevacaine 2 mg per kg body weight solution 0.5% is injected locally at the incision site by the surgical service.

##### Main outcome variables

Complications of anesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210515051299N1**

Registration date: **2021-05-24, 1400/03/03**

Registration timing: **prospective**

Last update: **2021-05-24, 1400/03/03**

Update count: **0**

##### Registration date

2021-05-24, 1400/03/03

##### Registrant information

###### Name

sheida shabanian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3222 0016

###### Email address

shabanian23@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparision between of Ropivacaine and Lidocain with Epinephrin in patient undergoing cleft palate repair

##### Public title

Comparision between of Ropivacaine and Lidocain with Epinephrin in patient undergoing cleft palate repair

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Candidate for cleft palate surgery

**Exclusion criteria:**  
Allergy to local anesthetics, and bleeding disorders  
Bleeding disorders Cardiovascular disorders Brain disorders

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

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization list will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Relevant drugs will be prepared and coded by the pharmacist (research project consultant) and the researcher will be unaware of the type of drug prescribed to the patient.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of 20 people in each group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Beheshti University of Medical Sciences

##### Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2021-05-02, 1400/02/12

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1400.055

## 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

Complications of anesthesia, including heart rate, blood pressure and anesthesia.

#### Timepoint

During anesthesia

#### Method of measurement

check of vital sign

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: lidocaine 2 mg per kilogram of body weight with epinephrine 1/80000 is injected locally at the incision site by the surgical service.

#### Category

Prevention

### 2

#### Description

Intervention group2: ropivacaine Lidocaine 2 mg per kilogram of body weight solution 0.5% is injected locally at the incision site by the surgical service

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mofid Hospital

##### Full name of responsible person

Eghbali Ahmad

##### Street address

Mofid children hospital, Shariati Av, Tehran

**City**  
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15468-15514  
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+98 21 3333 0006  
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eghbali@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Seyed Ali Ziai  
**Street address**  
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran  
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1985717434  
**Phone**  
+98 21 2243 9951  
**Email**  
msp@sbmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Eghbali Ahmad  
**Position**  
Assistant professor  
**Latest degree**

Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

#### Contact

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Assistant professor  
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## Person responsible for updating data

#### Contact

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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