

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Comparison of the effect of adding Dexamethasone and Dexmedetomidine to Bupivacaine infiltration on cleft lip surgery pain

#### Protocol summary

##### Study aim

Reduce pain

##### Design

This study is a double-blind clinical trial in which patients will be randomly divided into three treatment groups.

##### Settings and conduct

Imam Hossein Children Educational and Medical Center in 1401

##### Participants/Inclusion and exclusion criteria

includ criteria: Age between 3 and 10 months  
Candidate of unilateral cleft lip of both sexes The first operation is lip cleft Duration of surgery less than 2 hours  
ASA patients have I and II Parents must complete the study entry consent form  
exclud criteria: The surgery lasts more than 2 hours Hemodynamic changes require therapeutic action Re-need for topical injection of epinephrine at the site of surgery Reaction to any of the drugs studied

##### Intervention groups

Group A combined epinephrine 1200000, 1 cc bupivacaine 0.5% and 0.1 mg / kg dexamethasone to a total volume of 2 cc, and group B combined epinephrine 1200000, 1 cc bupivacaine 0.5% and 0.5 µg / kg dexmedetomidine to a total volume of 2 cc And group C epinephrine 1200000, 1 cc of bupivacaine 0.5% to the total volume of 2 cc in the stand

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220312054261N1**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

##### Registration date

2022-04-03, 1401/01/14

##### Registrant information

###### Name

Iman Reisi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3223 9619

###### Email address

iman.reeisy@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-11-22, 1401/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of adding Dexamethasone and Dexmedetomidine to Bupivacaine infiltration on cleft lip surgery pain

##### Public title

effect of adding Dexamethasone and Dexmedetomidine to Bupivacaine infiltration

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**  
 Age between 3 and 10 months Candidate of unilateral cleft lip of both sexes The first operation is lip cleft Duration of surgery less than 2 hours ASA patients have I and II Parents must complete the study entry consent form.

**Exclusion criteria:**  
 The surgery lasts more than 2 hours Hemodynamic changes require therapeutic action Re-need for topical injection of epinephrine at the site of surgery Reaction to any of the drugs studied

**Age**  
 From **3 months** old to **10 months** old

**Gender**  
 Both

**Phase**  
 3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
 Target sample size: **75**

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

**Randomization description**  
 The lottery is used for randomization and is adjusted based on the patients' national code number. The national number of patients is prepared and each number is written on a piece of paper, then drawn (one of the nurses in the study is asked to shuffle the sheets in a cup and one by one The first 25 people will be in the first group, the second 25 people will be in the second group and the rest of the patients will be in the third group.

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

**Blinding description**  
 The method of blinding is double-blind. The main researcher prepares the drugs in the appropriate dose in a specific syringe and the surgeon injects the drug into the site of the cleft lip without knowing the content of the drug, and the person who records the parameters and Collects does not know the type of drugs.

**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**  
 Hezar Jerib Street, Shiraz Gate Square  
**City**  
 Isfahan  
**Province**  
 Isfahan  
**Postal code**  
 81746-73461  
**Approval date**  
 2022-03-05, 1400/12/14  
**Ethics committee reference number**  
 IR.MUI.MED.REC.1400.826

## Health conditions studied

### 1

#### Description of health condition studied

the pain

#### ICD-10 code

G89.29

#### ICD-10 code description

Other chronic pain

## Primary outcomes

### 1

#### Description

Need to Tranquilizer

#### Timepoint

Preoperative, postoperative, 24 hours postoperative

#### Method of measurement

Using the scale of face, legs, activity, crying and comfort, which is one of the most common and widely used scales of observational-behavioral pain.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: epinephrine 1200000, 1 cc bupivacaine 0.5% and 0.1 mg / kg dexamethasone with a total volume of 2 cc- Drops of dexamethasone ampoules 8 mg / 2 ml [Raha Pharmacy]- bupivacaine -agutant vial 0.5% 20 ml [Exir Pharmacy]

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: epinephrine 1200000, 1 cc of bupivacaine 0.5% and 0.5 µg / kg of dexmedetomidine with a total volume of 2 cc - Madonex vial 200 micrograms / 2 ml [Exir Pharmacy]- Epinephrine DP

0.01% 10 ml ampoule[Drug Distributor - Factory]

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group: epinephrine 1200000, 1 cc of bupivacaine 0.5% to a total volume of 2 cc

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Hossein Children Educational and Medical Center

**Full name of responsible person**

Sedighe Shahhosseini

**Street address**

Imam Khomeini street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3386 6266

**Email**

emamhossein\_hospital@mui.ac.ir

**Web page address**

http://www.ehuch.mui.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Sedighe Shahhosseini

**Street address**

Imam Khomeini street

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**Province**

Isfahan

**Postal code**

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**Email**

emamhossein\_hospital@mui.ac.ir

**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**

10

**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**

Sedighe Shahhosseini

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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nasrin20ir@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Iman Reisi

**Position**

fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Position**

fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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003131285696

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Iman.reeisy@gmail.com

**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