

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

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Isfahan

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81746-73461

Phone

+98 31 3386 6266

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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

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Phone

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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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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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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