

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziai
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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
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Person responsible for updating data

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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