Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the effects of Dexmedetomidine and remifentanil on emergence of agitation in children with sevoflurane anesthesia

Protocol summary

Study aim

We aim to compare the effect of dexmedetomidine and remifentanil on postoperative sedation score and postoperative pain after general anesthesia with sevoflurane.

Design

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 90 children who candidate for strabismus surgery under general anesthesia with sevoflurane will be enrolled in the study. Eligible patients will be randomly allocated into three equal A, B and C groups by simple randomization.

Settings and conduct

This study will be done in operating room. All of the drugs solution (dexmedetomidine, remifentanil and placebo) of this study will be prepared in 10 ml syringes that are the same in shape by only one person who is aware of study's grouping. Anesthesiologist, patients and all medical stuffs that will collaborate in the study will not aware of the drug allocated to each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who will candidate for strabismus surgery under general anesthesia with sevoflurane. Non-inclusion criteria: history of: renal disease; liver disease; use of sedative drugs; mental retardation ;psychiatric disorder; allergy to drugs will be used in this study; those who needs rapid sequence induction

Intervention groups

Intervention group 1: this group will be received an IV infusion of dexmedetomidine 0.1 mcg/Kg over five minutes with a 10 ml syringe with the label A. Intervention group 2: patients in this group will receive IV infusion of remifentanyl, 0.1 mcg/Kg over five minutes with a 10 ml syringe with the label B. Control group: patients in this group will receive IV infusion of physiologic saline with a 10 ml syringe with the label C over five minutes.

Main outcome variables

Intraoperative hemodynamic parameters, emergence of agitation, postoperative pain, satisfaction of recovery stuff from children condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121204011662N14**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **prospective**

Last update: **2020-03-28, 1399/01/09**
Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effects of Dexmedetomidine and remifentanil on emergence of agitation in children with sevoflurane anesthesia

Public title
Comparison the effects of two anesthetic drugs on agitation of children after anesthesia.
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who will candidate for strabismus surgery under general anesthesia
Exclusion criteria:
Patients with history of congenital heart disease Patients with history of renal disease Patients with history of liver disease Patients who needs rapid sequence induction Patients with history use of sedative drugs Patients with history of mental retardation Patients with history of psychiatric disorder Patients with history of allergy to drugs will be used in this study.
Age
From **2 years** old to **7 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly allocated into three groups by block randomization. In this technique, permutation block of size 6 will be made for patients of three groups A, B & C. In each block equal numbers for three groups will be considered in alternative positions. Then 15 blocks of size 6 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blindness, All of the drugs solution (dexmedetomidine, remifentanil and normal saline) of this study will be prepared in 10 ml syringes that are similar and equal in shape, by a nurse of anesthesia who is aware of patients' grouping. These syringes will have label A , B or C. Anesthesiologist who will use these syringes will not aware of the content of these syringes, and just will use syringes with label A for patients in group A, syringes with label B for patients in group B and syringes with label C for patients in group C. Patients and all medical stuffs who will collaborate in data gathering, will not be aware of the content of these syringes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz Medical School
Street address
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
197871345
Approval date
2020-02-24, 1398/12/05
Ethics committee reference number
IR.SUMS.MED.REC.1398.647

Health conditions studied

1

Description of health condition studied
Post operative agitation in children
ICD-10 code
R45.1
ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Postoperative agitation
Timepoint
At times: 0, 10 min, 20 min , 30 min after arrival in recovery room.
Method of measurement
Pediatric anesthesia emergence delirium scale .

2

Description

Postoperative pain severity

Timepoint

At times: 0, 10 min, 20 min , 30 min after arrival in recovery room.

Method of measurement

Children and infants postoperative pain scale

Secondary outcomes

1

Description

Mean arterial blood pressure (MAP)

Timepoint

Preoperative, Intraoperative, Postoperative.

Method of measurement

Non invasive blood pressure monitoring by digital blood pressure measuring of monitoring system.

2

Description

Heart rate per minute

Timepoint

Preoperative, Intraoperative, Postoperative.

Method of measurement

Electrocardiogram

3

Description

Satisfaction of the recovery room stuff from children condition.

Timepoint

At the end of recovery stay.

Method of measurement

Patient's files and records

Intervention groups

1

Description

Intervention group 1: At the end of anesthesia, patients in group A will receive IV dexmedetomidine 0.1 mcg /Kg over five minutes with a 10 ml syringe with the label A.

Category

Treatment - Drugs

2

Description

Intervention group 2: At the end of anesthesia, patients in group B will receive IV infusion of remifentanyl 0.1 mcg/Kg over five minutes with a 10 ml syringe with the label B.

Category

Treatment - Drugs

3

Description

Control group: At the end of anesthesia, patients in group C will receive 10 ml of IV normal saline over five minutes with a 10 ml syringe with the label C.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili training and medical center.

Full name of responsible person

Mohamma Ali Sahmeddini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
MohammadAli Sahmeddini

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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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