

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 2026

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

#### Protocol summary

##### Study aim

We aim to compare the effect of dexmedetomidine and remifentanyl 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, remifentanyl 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)

##### Phone

+98 71 1231 8072

##### Email address

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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.

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**Province**

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**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 staff 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  
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MohammadAli Sahmeddini  
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## Person responsible for scientific inquiries

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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