

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of two anesthetic regimens Pofol-Lidocaine and Thiopental - Lidocaine on control of emergence agitation due to Sevoflurane in children

#### Protocol summary

##### Summary

We conducted a double blind Randomised Clinical Trial to study the effect of intravenous Lidocaine on emergence agitation of Sevoflurane in children with retinoblastoma undergoing eye examination under general anesthesia. 120 children with retinoblastoma that met the inclusion criteria were randomly divided into 4 groups (using block randomization). There were 30 cases in each group. Group 1: Sodium Thiopental \_Lidocaine, Group 2: Pofol \_Lidocaine, Group 3: Sodium Thiopental \_Saline, Group 4: Pofol \_Saline After monitoring, Sevoflurane with Minimal Alveolar Concentration (MAC) of %4 was administered for induction. After inserting an iv canula Thiopental Sodium was injected (5Mg/Kg) for groups 1 and 2, and Pofol was injected for groups 3 and 4, (2Mg/Kg). Immediately after examination, Lidocaine (1.5mg/kg) was administered for groups 1 and 3, and saline was administered for groups 2 and 4 with same dose. Finally, agitation rate was determined by anesthesiologist. Patient and anesthesiologist were not aware of the type of drugs and only operating room technician was aware of prescribed drugs for patients (blindness). Anesthesiologist divided children into 5 levels based on agitation: 1. Asleep; 2. Awake and calm; 3. Irritable or consolable crying; 4. Inconsolable crying; and 5. Severe restlessness. The scores were recorded every 10 minutes after transfer of patients into recovery and compared in the four groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013072914199N1**

Registration date: **2013-09-23, 1392/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-09-23, 1392/07/01

##### Registrant information

###### Name

Leila Mounesan

###### Name of organization / entity

Tehran University of Medical Sciences

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##### Recruitment status

###### Recruitment complete

##### Funding source

Research Deputy of Tehran University of Medical Sciences

##### Expected recruitment start date

2012-03-22, 1391/01/03

##### Expected recruitment end date

2013-07-21, 1392/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of two anesthetic regimens Pofol-Lidocaine and Thiopental - Lidocaine on control of emergence agitation due to Sevoflurane in children

##### Public title

The effect of Lidocaine on control of emergence agitation due to Sevoflurane

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Parent willingness to participate in the study and informed consent, Age group: 12 to 36 months, Retinoblastoma eyes Exclusion criteria: A history of seizures, Liver disease, Kidney disease, Heart disease, Having a cold during the current week, Sensitivity to Lidocaine, Intense crying

### **Age**

From **1 year** old to **3 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

##### **Street address**

Fourth Floor, No.23 ,16th Azar Ave., Keshavarz Blvd., Tehran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2012-05-13, 1391/02/24

#### **Ethics committee reference number**

90/2799/130/5

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Agitation

### **ICD-10 code**

R45.1

### **ICD-10 code description**

Restlessness and agitation

## **Primary outcomes**

### 1

#### **Description**

Agitation

#### **Timepoint**

The scores were recorded every 10 minutes (In the first 30 minutes after entering into recovery), since the children transferred to recovery

#### **Method of measurement**

Anesthesiologist divided children into 5 levels based on agitation: 1. Asleep; 2. Awake and calm; 3. Irritable or consolable crying; 4. Inconsolable crying; and 5. Severe restlessness

## **Secondary outcomes**

### 1

#### **Description**

Nausea and vomiting

#### **Timepoint**

The symptoms were recorded every 10 minutes (In the first 30 minutes after entering into recovery), since the children transferred to recovery

#### **Method of measurement**

Observation

## **Intervention groups**

### 1

#### **Description**

Group2: Pofol 2mg/kg and Lidocaine 1.5mg/kg Pofol administration: IV, Frequency of use: Once and after induction of anesthesia with sevoflurane to maintain anesthesia, Manufacturer: Germany Lidocain administration: IV, Frequency of use: Once or immediately after an eye examination Manufacturer: Rasht - Iran

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Group1: Was administered Sodium Thiopental 5mg/kg and Lidocaine 1.5mg/kg Lidocain administration: IV, Frequency of use: Once or immediately after an eye examination Manufacturer: Rasht - Iran Sodium Thiopental administration: IV, Frequency of use: Once and after induction of anesthesia with sevoflurane to maintain anesthesia, Manufacturer: India

#### **Category**

Treatment - Drugs

### 3

#### Description

Group3: Was administered Sodium Thiopental 5mg/kg and an equivalent amount of Saline Sodium Thiopental administration: IV, Frequency of use: Once and after induction of anesthesia with sevoflurane to maintain anesthesia, Manufacturer: India

#### Category

Treatment - Drugs

### 4

#### Description

Group4: Pofol 2mg/kg and an equivalent amount of Saline Pofol administration: IV, Frequency of use: Once and after induction of anesthesia with sevoflurane to maintain anesthesia, Manufacturer: Germany

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul Akram Hospital

##### Full name of responsible person

Dr.Hamidreza Faiz

##### Street address

Eye surgery, Rasool Akram Hospital, Niyaesh Ave., Sattar Khan St., Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Council of Tehran University of Medical Sciences

##### Full name of responsible person

Dr.Akbar Fotouhi

##### Street address

Sixth Floor, Qods St., Keshavarz Blvd., Tehran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Research Council of Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rasoul Akram Hospital

##### Full name of responsible person

Dr. Hamidreza Faiz

##### Position

Anesthesiologist. Assistant

##### Other areas of specialty/work

##### Street address

Department of anesthesiology, Rasool Akram Hospital, Niyaesh Ave., Sattar Khan St., Tehran

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## Person responsible for updating data

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*