

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Impact of parental presence during induction of anesthesia on anxiety level among pediatric patients and their parents

#### Protocol summary

##### Summary

Anesthesia induction is a stressful event for children and their parents, and may have potentially harmful consequences to the patient's physiological and mental situation. Traumatic anesthesia induction has psychological consequences that recur with repeated anesthesia, increase pediatric discomfort during the recovery period, and may even induce reactionary postoperative behavior. The aim of this study is to assess the impact of parental presence during induction of anesthesia on anxiety scores in pediatric patients. This clinical trial will be performed on two groups of 48 children with ASA 1 and 2 undergoing elective minor surgery at Mofid Children Hospital. Parents unwilling to continue the study will be excluded. Both groups will receive Midazolam 0.5 mg/kg at least 20 minutes before surgery but in case group one of the parents will be present in the operating room until induction of anesthesia and loss of consciousness of the patient. Anxiety in children (m-YPAS), parental anxiety (STAI), cooperation of patient with anesthesiologist at induction of anesthesia (ICC) and parental satisfaction (VAS) will be measured. Data collected in two groups will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011931497N4**  
Registration date: **2017-02-16, 1395/11/28**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-02-16, 1395/11/28

#### Registrant information

##### Name

Afsaneh Sadeghi

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2290 8383

##### Email address

af.sadeghi@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shahid Beheshti University of Medical Sciences

#### Expected recruitment start date

2017-02-19, 1395/12/01

#### Expected recruitment end date

2017-05-22, 1396/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Impact of parental presence during induction of anesthesia on anxiety level among pediatric patients and their parents

#### Public title

Impact of parental presence on preoperative anxiety of children

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: patients age 4-10 years with ASA 1 or 2 without history of psychiatric disorders and drugs undergoing elective minor surgery such as inguinal or

umbilical hernias ;surgeries less than 1-hour duration  
with no significant changes in the patient's  
hemodynamic parameters Exclusion criteria:Parents  
unwilling to continue the study

#### **Age**

From **4 years** old to **10 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **96**

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

Randomized

#### **Randomization description**

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

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

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

Shahid Beheshti University of Medical Science

###### **Street address**

Arabi Ave,Daneshjoo Blvd,Velenjak Ave

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2010-07-04, 1389/04/13

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

87/225

### **Health conditions studied**

#### **1**

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

Anxiety

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

F41.9

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

Anxiety disorder, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Preoperative anxiety in children

##### **Timepoint**

At ward,at preparation room and immediately before  
induction of anesthesia

##### **Method of measurement**

Modified Yale Preoperative Anxiety Scale

#### **2**

##### **Description**

Parental anxiety

##### **Timepoint**

At ward,at preparation room,immediately before  
induction of anesthesia

##### **Method of measurement**

State And Trait Anxiety Scale

### **Secondary outcomes**

#### **1**

##### **Description**

Cooperation of child with anesthesiologist at induction of  
anesthesia

##### **Timepoint**

At induction of anesthesia

##### **Method of measurement**

Induction Compliance Checklist

#### **2**

##### **Description**

parental satisfaction

##### **Timepoint**

After induction of anesthesia

##### **Method of measurement**

visual analog scale

### **Intervention groups**

#### **1**

##### **Description**

In control group there is no intervention

##### **Category**

N/A

#### **2**

##### **Description**

In intervention group,parents are present at induction of  
anesthesia until loss of consciousness.

##### **Category**

Other

### **Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Mofid Children Hospital

**Full name of responsible person**

Afsaneh Sadeghi

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afsaneh Sadeghi

**Street address**

Arabi Ave,Daneshjoo Blvd,Velenjak Ave

**City**

Tehran

**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**

*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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afsaneh Sadeghi

**Position**

Anesthesiologist

**Other areas of specialty/work**

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**Phone**

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**Fax**

**Email**

**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*