

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison the effect of intranasal dexmedetomidine and remifentanil on reduction of hemodynamic changes after intubation in children ages 6 to 12 years old under general anesthesia

#### Protocol summary

##### Study aim

Comparison the effect of intranasal dexmedetomidine and remifentanil on reduction of hemodynamic changes after intubation in children ages 6 to 12 years old under general anesthesia

##### Design

This study is a double-blind, randomized, clinical trial study. The minimum required sample size was determined using the formula 35 in each group. Patients are classified into three groups using the random numbers table.

##### Settings and conduct

This clinical trial study will be done at Imam Hossein Hospital in Isfahan. The way of blinding is that the drugs are prepared and encoded in similar syringes and similar volumes. And the researcher and the anesthetist and the patient do not know about the location of the patients in the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria includes all children ages 6 to 12 years of age who have a general anesthetic candidate with ASA I and ASA II grades and are satisfied with the patient's parents to participate in the study. The criteria for not attending the study include children under 6 years of age and over 12 years of age, underlying illness (inherited and genetic diseases, metabolic diseases, etc.), and parents' disagreement for participation in the study.

##### Intervention groups

Intervention group 1: Two minutes before anesthesia induction received 4 µg / kg of Intranasal remifentanil. Intervention group 2: Two minutes before anesthesia induction, 2 µg / kg intranasal Dexmedetomidine will receive. Control group: Two minutes before anesthesia induction, 1cc of intranasal normal saline will receive.

##### Main outcome variables

Hemodynamic change( systolic blood pressure; diastolic blood pressure; mean arterial blood pressure and heart

rate)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160301026866N7**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **prospective**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

##### Registration date

2018-09-04, 1397/06/13

##### Registrant information

##### Name

Amir Shafa

##### Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3627 2655

##### Email address

amir\_shafa@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of intranasal dexmedetomidine and remifentanyl on reduction of hemodynamic changes after intubation in children ages 6 to 12 years old under general anesthesia

**Public title**

Intranasal Dexmedetomidine and Remifentanyl and hemodynamic changes after intubation in children

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Inclusion criteria: all children ages 6 to 12 years of age with general anesthetics, ASA I and ASA II grades, and consent from the parents of the patient to participate in the study.

**Exclusion criteria:**

The criteria for not attending the study include children under 6 years of age and over 12 years of age, underlying illness (inherited and genetic diseases, metabolic diseases, etc.), and parents' disagreement for participation in the study

**Age**

From **6 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization based on random number tables

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Medications are prepared and encoded in syringes of equal volume, Drugs are prescribed by an anesthetist who is not known to the groups. The consequences of prescribing the drug are recorded by the researcher.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8185665843

**Approval date**

2017-09-02, 1396/06/11

**Ethics committee reference number**

ir.mui.rec.1396.3.091

**Health conditions studied****1****Description of health condition studied**

Hemodynamic and Respiratory complications after intubation

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Hemodynamic change

**Timepoint**

One minute after the drug is given and one minute after the intubation

**Method of measurement**

Anesthetic monitoring device

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: Two minutes before anesthesia induction received 4 µg / kg of Intranasal remifentanyl .Intervention group 2: Two minutes before anesthesia induction, 2 µg / kg intranasal Dexmedetomidine will receive .Control group: Two minutes before anesthesia induction, 1cc of intranasal normal saline will receive.

**Category**  
Treatment - Drugs

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Emamhossein hospital  
**Full name of responsible person**  
Amir Shafa  
**Street address**  
Emamhossein hospital, Emamkhomeini Ave.  
**City**  
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8185665843  
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+98 13 3773 5509  
**Email**  
shafa\_amir@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Shaghayegh haghjoo  
**Street address**  
Isfahan University of Medical Sciences, Hezarjrib Ave  
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**Email**  
sh\_haghjoo@med.mui.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Esfahan 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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Amir Shafa  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**

Amir Shafa

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Province**

Isfahan

**Postal code**

8185665843

**Phone**

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**Email**

shafa\_amir@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The total data can be shared after Unidentifiable people

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Free access

**Under which criteria data/document could be used**

Accessible for everyone without a precondition

**From where data/document is obtainable**

Amir Shafa: shafa\_amir@yahoo.com

**What processes are involved for a request to access data/document**

Request via email

**Comments**