

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

**The clinical study of local anesthesia injection effects on recovery condition for children under 6 years that they reference to the surgery room of dental school.**

### Protocol summary

#### Summary

The aim of study is supportive care by local anesthesia on recovery in children subsequent treatment of dentistry under general anesthesia. In this study 60 healthy children under 6 years that they candidate for treatment of dentistry are divided in to two groups at random (A control groups and an intervention one). The assessment before action and the method of anesthesia for all done the same. Infiltration of local anesthesia is done in one of the groups while in the other one isn't. Recovery conditions: Includes the time of recovery; Pain and agitation. The children are evaluated and compared in two groups. Entry condition: The children 's parents are explain about entry the study and if they like to cooperate they can complete the special form; The children must be under 6 years; Healthy or ASA I; Assigned to dental treatment for general anesthesia; Exit condition: Patient with ASA II or more; Bleeding disorder; Parents disagreement; Systematic and chronic hepatic and renal disease; The time of general anesthesia less than 60 or more than 90 minutes; Using sedate or sedation drug by the children interfering.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201107164224N11**

Registration date: **2011-09-06, 1390/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2011-09-06, 1390/06/15

#### Registrant information

#### Name

Nasser Kaviani

#### Name of organization / entity

#### Country

Iran (Islamic Republic of)

#### Phone

+98 31 1792 2858

#### Email address

kaviani@dnt.mui.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research, Esfehan University of Medical Sciences

#### Expected recruitment start date

2011-03-16, 1389/12/25

#### Expected recruitment end date

2011-07-09, 1390/04/18

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The clinical study of local anesthesia injection effects on recovery condition for children under 6 years that they reference to the surgery room of dental school.

#### Public title

A study of local anesthesia injection effects on recovery condition for children following dentistry under general anesthesia

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Entry condition: The children 's parents are explain about

entry the study and if they like to cooperate they can complete the special form; The children must be under 6 years; Healthy or ASA I; Assigned to dental treatment for general anesthesia; Exit condition: Patient with ASA II or more; Bleeding disorder; Parents disagreement; Systematic and chronic hepatic and renal disease; The time of general anesthesia less than 60 or more than 90 minutes; Using sedate or sedation drug by the children interfering.

#### **Age**

From **2 years** old to **6 years** old

#### **Gender**

Both

#### **Phase**

2-3

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

*No information*

#### **Sample size**

Target sample size: **60**

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

Randomized

#### **Randomization description**

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

Single 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 Esfahan University of Medical Science

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

Hezar Jarib street, University of Medical Science, Esfahan

###### **City**

Esfahan

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

##### **Approval date**

2011-04-12, 1390/01/23

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

390175

### **Health conditions studied**

#### **1**

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

A study of local anesthetic injection effects on recovery condition for children following general anesthesia

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

f10,f11,f1

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

Mental and behavioural disorders due to psychoactive substance use

### **Primary outcomes**

#### **1**

##### **Description**

Recovery condition

##### **Timepoint**

Evry ten minutes

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

Obsevation

### **Secondary outcomes**

#### **1**

##### **Description**

Discharge time

##### **Timepoint**

Evry ten minutes

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

Observation and examination

### **Intervention groups**

#### **1**

##### **Description**

Intervention groups: In this study 60 healthy children are divided in to two groups at random. The assessment before action and the method of anesthesia for all done the same. Injection of local anesthesia like Lidocain 2%(vial 1.8 c.c) that used once or three more in 5 minutes is done in intervention groups.

##### **Category**

Behavior

#### **2**

##### **Description**

Control groups: In this study 60 healthy children are divided in to two groups at random. The assessment before action and the method of anesthesia for all done the same. Injection of local anesthesia like Lidocaine is not done in control groups.

##### **Category**

Behavior

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Surgery room, Dentistry college, University Medical of Science, Esfahan

**Full name of responsible person**

Nasser Kaviani

**Street address**Dental college, Esfahan University Medical of Science,  
Esfahan**City**

Esfahan

**Position**

Anesthesiologist, Assistant professor

**Other areas of specialty/work****Street address**Dental school, University Medical of Sciences, Hezar  
Jarib street, Esfahan, IRAN**City**

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Kaviani@dnt.mui.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Esfahan University of  
Medical Sciences**Full name of responsible person**

Amin Alla Tavangar

**Street address**Esfahan dental college, Hezar Jarib street, University  
Medical of Science, Esfahan, IRAN**City**

Esfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

**Title of funding source**Vice chancellor for research, Esfahan 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan dental school

**Full name of responsible person**

Nasser Kaviani

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan dental school

**Full name of responsible person**

Masod Gheisary

**Position**

Dentistry collegian

**Other areas of specialty/work****Street address**Dental school, University Medical of Sciences, Hezar  
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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*