

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 addressDental 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**

Esfahan

Postal code**Phone**

+98 31 1792 2851

Fax**Email**

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 addressEsfahan 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 sourceVice 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
Jarib street, Esfahan, IRAN**City**

Esfahan

Postal code**Phone**

+98 31 1792 2858

Fax**Email**

Md_gheisary@yahoo.com

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*