

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Efficacy of intravenous infusion of Dexmedetomidine in the first ten minutes of surgery in comparison with last ten minutes of surgery on post operative agitation in 9 to 96 months aged children undergoing oral surgery

Protocol summary

Summary

Objective: To evaluate the efficacy of intravenous infusion of Dexmedetomidine in the first ten minutes of surgery in comparison with last ten minutes of surgery on post operative agitation in children undergoing oral surgeries Design: Single blind randomized clinical trial Setting: Children undergoing oral surgeries in Mofid Children Hospital Inclusion criteria: patients with class 1 according to the American Society of Anesthesiology (ASA) scoring criteria; Age of 9 months to 96 months Exclusion criteria: Parental disagreement Intervention: Eighty children undergoing oral surgeries will be randomly allocated to one of the two parallel groups. In the group 1 after induction of anesthesia Dexmedetomidine will be started with 1 µg/kg intravenous infusion during 10 minutes. In the group 2 Dexmedetomidine will be started with 1 µg/kg intravenous infusion during 10 minutes in the last ten minutes of surgery. Anesthesia method is similar between two groups. Primary outcome: Level of agitation in the recovery room using Ramsay scale Secondary outcome: Mean arterial blood pressure every 5 minutes; Heart rate every 5 minutes; Anesthesia time; Surgical time; Extubation time; Recovery time; Severity of pain in the recovery room using FLACC (Face, Legs, Activity, Cry, Consolability) pain scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122031497N1**
Registration date: **2017-03-31, 1396/01/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-31, 1396/01/11

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

2016-11-21, 1395/09/01

Expected recruitment end date

2017-01-21, 1395/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of intravenous infusion of Dexmedetomidine in the first ten minutes of surgery in comparison with last ten minutes of surgery on post operative agitation in 9 to 96 months aged children undergoing oral surgery

Public title

The effect of Dexmedetomidine on post operative agitation in children undergoing oral surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with class 1 according to the American Society of Anesthesiology (ASA) scoring criteria; Age of 9 months to 96 months Exclusion criteria: Parental disagreement

Age

From **9 months** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak Ave

City

Tehran

Postal code

1916964913

Approval date

2016-10-31, 1395/08/10

Ethics committee reference number

ir.sbm.u.msp.rec.1395.281

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

After surgery in the recovery room

Method of measurement

Ramsay sedation scale

Secondary outcomes**1****Description**

Mean arterial blood pressure

Timepoint

Every five minutes

Method of measurement

Millimeter of mercury announced by vital sign monitoring system

2**Description**

Heart rate

Timepoint

Every five minutes

Method of measurement

Heart rate announced by vital sign monitoring system

3**Description**

Anesthesia time

Timepoint

Start of induction of anesthesia until extubation

Method of measurement

Minute

4**Description**

Surgical time

Timepoint

Since the start of the operation until the end of the operation

Method of measurement

Minute

5**Description**

Extubation time

Timepoint

After discontinuation of anesthetic gas until extubation

Method of measurement

Minute

6

Description

Recovery time

Timepoint

From entrance of patient to recovery room until discharge from recovery room

Method of measurement

Minute

7

Description

FLACC (Face, Legs, Activity, Cry, Consolability) pain scale at recovery

Timepoint

After surgery in the recovery room

Method of measurement

FLACC (Face, Legs, Activity, Cry, Consolability) scale

Intervention groups

1

Description

Dexmedetomidine, 1 µg/kg intravenous infusion, first ten minutes of surgery

Category

Treatment - Drugs

2

Description

Dexmedetomidine, 1 µg/kg intravenous infusion, last ten minutes of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children Hospital

Full name of responsible person

Afsaneh Sadeghi

Street address

Shariati Ave

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

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak Ave

City

Tehran

Postal code

Phone

+98 21 2290 8383

Fax

Email

af.sadeghi@sbmu.ac.ir

Web page address

Person responsible for scientific 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

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak Ave

City

Tehran

Postal code

Phone
+98 21 2290 8383
Fax
Email
af.sadeghi@sbmu.ac.ir
Web page address

+98 21 2290 8383
Fax
Email
af.sadeghi@sbmu.ac.ir
Web page address

Person responsible for updating data

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
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak Ave
City
Tehran
Postal code
Phone

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