Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Dexmedethomidine will be started with 1 µg/kg intravenous infusion during 10 minutes. In the group 2 Dexmedethomidine 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

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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 Dexmedethomidine 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.sbmu.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
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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
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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
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Person responsible for updating data

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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