Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Dexamethasone to prevent Propofol injection pain in children 6 to 13 years old in elective surgery Birjand Valiasr hospital and Emamreza hospital in 2016

Protocol summary

Summary

This randomized, double-blind, controlled with placebo, in order to determine the Effect of Dexamethasone to prevent Propofol injection pain in children 6 to 13 years old in elective surgery Birjand Valiasr hospital and Emamreza hospital in 2016 will be carried out. A study of 50 children undergoing elective surgery done. Inclusion criteria: children aged 6 to 13 years undergoing elective surgery (tonsillectomy, adenotonsillectomy, adenoctomy, lower extremity fractures). Exclusion criteria included children crying when entering the operating room; emergency; abnormal liver and renal function; musculoskeletal disorders and allergy to Propofol; Dexamethasone and also entering an intravenous line in the back of their hand are impossible. Patients enrolled were randomly assigned to one of two groups, study group and control. In both groups of patients with venous cannula (22) is taken. Under the same conditions to all patients two hours before surgery 0/2 mg Midazolam (oral) as Prymdykyshn and 20 cc juice is prescribed. Then 6 ml per kg intravenous Sugar solution (2 / 3,1 / 3) infusion. At study group 0/15 mcg per kg Dexamethasone and the control group with the same volume of Normal Saline injected. Then induction dose of Propofol 1% to just 20% of all patients, infusion and injection pain by Face Pain Scale (FPS) with rating (0 to 10) is measured and recorded. The remainder of the dose of Propofol and Fentanyl Atracurium injected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011325992N1**
Registration date: **2016-02-19, 1394/11/30**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-02-19, 1394/11/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-03-29, 1395/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Dexamethasone to prevent Propofol injection pain in children 6 to 13 years old in elective surgery Birjand Valiasr hospital and Emamreza hospital in 2016

Public title

Effect of Dexamethasone to prevent Propofol injection

pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Children ages 6 to 13 years undergoing elective surgery (tonsillectomy, adenotonsillectomy, adenoctomy, lower extremity fractures). Exclusion criteria: included children crying when entering the operating room; emergency; abnormal liver and renal function; musculoskeletal disorders and allergy to Propofol, Dexamethasone; and also entering an intravenous line in the back of their hand are impossible.

Age
From **6 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences

Street address
Birjand, Birjand University of Medical Sciences.

City
Birjand

Postal code

Approval date
2015-10-04, 1394/07/12

Ethics committee reference number
ir.bums.1394.45

Health conditions studied

1

Description of health condition studied
Propofol injection pain

ICD-10 code
R52

ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Facial expressions child

Timepoint
Immediatly after the injection 20% of the doss of Propofol anesthesia

Method of measurement
Face Pain Scale (FPS) with rating (0 to 10)

2

Description
Heart rate of patient

Timepoint
Before Dexamethasone and Normal Saline injection and after administration of anesthesia Propofol dose by 20%

Method of measurement
In bits per minute using ECG

Secondary outcomes

1

Description
Injection site pain, redness, injection site phlebitis

Timepoint
After transferring the patient to recovery

Method of measurement
Visit the site of injection

Intervention groups

1

Description
Study group: Injection of 0.15 micrograms per kilogram immediately before induction of anesthesia Propofol injection 20% .

Category
Treatment - Drugs

2

Description
Control group: Normal Saline at the same volume confounding medication immediately before induction of anesthesia Propofol infusion dose by 20%

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital of Birjand
Full name of responsible person
Dr seyed Hasan Karbasi
Street address
City
Birjand

2

Recruitment center
Name of recruitment center
Vali Asr hospital of Birjand
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Asghar Zarban
Street address
Birjand, Birjand University of Medical Sciences.
City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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

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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