

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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, adenectomy, 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

Name

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Name of organization / entity

Anesthesiology

Country

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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, adenectomy, 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

Immediately 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

Dr seyed Hasan Karbasi

Street address**City**

Birjand

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

Contact**Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Hossein Hashemy

Position

Student Anesthesiology

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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