

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The evaluation of the effect of dexmedetomidine added to local infiltration of bupivacaine on post-operative pain of pediatric inguinal herniorraphy.

Protocol summary

Summary

Objective: To evaluate the effect of dexmedetomidine added to local infiltration of bupivacaine on post-operative pain of pediatric inguinal herniorraphy.

Research Design: Conduction of a randomized, double-blind, clinical trial. **Inclusion criteria:** Patients between the range of 6 months to 6 years old; (ASA I); patients who have surgery for unilateral inguinal hernia. **Exclusion criteria:** A history of bleeding disorders, allergies to Dexmedetomidine and bupivacaine; developmental delay; upper respiratory tract infection, congenital heart disease, liver and kidney failure, neurological disease, mental retardation. In the recovery (PACU) O2 Sat, heart rate and blood pressure will be monitored by a nurse every 15 minutes. Postoperative pain will be measured by an experienced nurse by children's and infant's postoperative pain scale (CHIPPS) immediately after arrival in recovery, 1 hour, 3 hours and 4 hours after the operation. And also sedation will be measured by sedation score immediately 1 hour, 2 hours, 3 hours and 4 hours after the arrival to recovery. Oral midazolam 0.5 mg/ kg will be used for sedation for all patients 30-20 minutes before transfer to the operating room. 6 milligrams per kilogram 1/3-2/3 solution is injected after entering the operating room. 7 milligrams per kilogram of sodium thiopental is injected for induction of anesthesia and sevoflurane 0.5-2% and oxygen and nitrous oxide by mask for maintenance. All patients will be monitored preoperatively and as same as the heart rate, EKG and systolic blood pressure (SBP) and arterial oxygen saturation (SPO2) every 5 minutes until the end of surgery. If there is more than 3 CHIPPS pain score, 15 mg / kg acetaminophen given intravenously, and ondansetron is administered if there is vomiting. In group (BD), (0.2 ml/kg and 0.5 % Bupivacaine while in group (BO), 0.5 ml/kg Bupivacaine 0.5% + 1 ml normal saline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060314372N8**

Registration date: **2016-12-18, 1395/09/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-18, 1395/09/28

Registrant information

Name

Simin Azemati

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of dexmedetomidine added to local infiltration of bupivacaine on post-operative pain of pediatric inguinal herniorrhaphy.

Public title

The evaluation of the effect of dexmedetomidine added to local infiltration of bupivacaine on post-operative pain of pediatric inguinal herniorrhaphy.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients between the range of 6 months to 6 years old; (ASA I); patients who have surgery for unilateral inguinal hernia. Exclusion criteria: A history of bleeding disorders, allergies to Dexmedetomidine and bupivacaine; developmental delay; upper respiratory tract infection, congenital heart disease, liver and kidney failure, neurological disease, mental retardation.

Age

From **6 months** 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)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Dexmedetomidine is from Origin Orion Pharma ,Germany

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code**Approval date**

2015-06-28, 1394/04/07

Ethics committee reference number

IR.SUMS.REC.1394.5.945

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Post-operative pain

Timepoint

children's and infant's postoperative pain scale (CHIPPS)

Method of measurement

Immediately after arriving in recovery, 1 hour, 2 hours, 3 hours and 4 hours after surgery

Secondary outcomes

1

Description

Sedation

Timepoint

Immediately after arriving in recovery, 1 hour, 2 hours, 3 hours and 4 hours after surgery

Method of measurement

Sedation score

Intervention groups

1

Description

BD,(Bupivacaine, Dexmedetomidine(Dexmedetomidine is from Origin Orion Pharma ,Germany) group 1 microgram per kilogram Dexmedetomidine 0.2 mg/ kg Bupivacaine 5% will be injected by a surgeon in the incision site .

Category

Treatment - Drugs

2

Description

in (BO) group 0.5 mg/ kg Bupivacaine 5% and 1 ml normal saline will be injected by a surgeon in the incision site.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Madar o Kodak Hospital

Full name of responsible person

Anahita Pourali

Street address

Madar o Kodak Hospitall, EmamReza Boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Anahita Pourali

Position

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Shiraz University Of Medical Sciences

Full name of responsible person

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Shiraz anesthesiology and critical care research center

Full name of responsible person

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Position

English Consultant

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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