Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Bupivacaine0.5% + 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
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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 herniorraphy.

Public title
The evaluation of the effect of dexmedetomidine added to local infiltration of bupivacaine on post-operative pain of pediatric inguinal herniorraphy.
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 HospitaIl, EmamReza Boulevard
City
Shiraz

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
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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English Consultant
Other areas of specialty/work
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masihifarzaneh@yahoo.com
Web page address

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