Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the analgesic effects of Ofsar and Lidocaine - Prilocaine ointments in relief of pain after inguinal hernia surgery

Protocol summary

Summary

The purpose of this study is to compare the effects of Ofsar and Lidocaine- Prilocaine ointments on pain relief after inguinal hernia surgery. This study will be done as a double-blind randomized controlled clinical trial on 50 patients with unilateral hernia. Bupivacaine is used as spinal anesthesia. Meanwhile, the patients will have an incision size less than 20 cm. Patients will be excluded if they have received analgesics before or during surgery. The patients will be randomly allocated into two groups. Patients in group A, will receive Ofsar ointment and Group B, will receive Lidocaine - Prilocaine ointment. Since this study is double blind, the packages which contained Ofsar and Lidocaine - Prilocaine ointments are coded as A and B. Neither patients, nurses nor physicians are aware of the type of ointment in the packages. After surgery, behind the incision area in the first group, Ofsar ointment and second group lidocaine - Prilocaine ointment are administered. In both groups, the pain severity will be measured by Numerical Rating Scale (NRS) and then 25 mg pethidine will be injected intravenously to patients. The ointments are administered every 8 hours. If pain persists, the pain severity is measured and injection of pethidine will be repeated. The patients will fill out a Numerical Rating Scale every 8 hours for the 48 hours after surgery. Pain severity and total amount of pethidine consumed, are recorded in the questionnaire. Analgesic effects of drugs will be determined by comparing pain reduction and also measuring the total amount of pethidine consumed in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212168729N5**
Registration date: **2014-09-07, 1393/06/16**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2014-09-07, 1393/06/16

Registrant information

Name

Seyed Mohammad Reza Javadi

Name of organization / entity

Hamadan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the analgesic effects of Ofsar and Lidocaine - Prilocaine ointments in relief of pain after inguinal hernia surgery

Public title

Comparison of the effects of Ofsar and Lidocaine - Prilocaine ointments on pain after surgery

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1. Patients with unilateral inguinal hernia who refer to Besat hospital 2. Incision size less than 20cm 3. General Anesthesia with endotracheal tube 4. Age more than 18 Exclusion criteria: 1. Patient under treatment of analgesics 2. Hypersensitivity to amides anesthetics 3. Patient who undergo nerve block except for epidural nerve block 4. Incarcerated and strangulated hernia
Age
From **18 years** old to **75 years** old
Gender
Male

Phase
3
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
Not used
Assignment
Parallel
Other design features
Based on gradual entering of samples the following method will be used for random selection and blinding of the study: Fifty dark packets numbered from 1 to 50 are given to the evaluating physician. A card is placed inside the packets with the label A or B. the A and B written on the packets will be designated using randomized numbers table. When the first patient refers, packet number 1 is opened by the evaluating physician and patient is allocated to the group designated within the packet. Neither the physician, nor the patient, nor the analyst are aware of the contents of the drugs and only our representative is aware. It should be noted that one of our colleagues is present in all the stages of extract, ointment production and coding. This colleague played no role in sampling and drug delivery to patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shaheed Fahmide Blvd., Hamadan, Iran
City
Hamadan
Postal code
Approval date
2013-04-30, 1392/02/10
Ethics committee reference number
16/35/9/264/D/P

Health conditions studied

1

Description of health condition studied
Inguinal hernia
ICD-10 code
K40.9
ICD-10 code description
Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
Pain
Timepoint
Every 8 hours during 48 hours after surgery
Method of measurement
Numerical Rating Scale

Secondary outcomes

1

Description
The total amount of pethidine consumed
Timepoint
During 48 hours after surgery
Method of measurement
Milligram (mg)

Intervention groups

1

Description
Intervention group1: Number of examinees: 25 After inguinal hernia repair, Ofsar ointment is applied to the incision margin every 8 hours for 48 hours and analgesic effect will be determined by NRS.
Category
Treatment - Drugs

2

Description
Intervention group2: Number of examinees: 25 After inguinal hernia repair, Lidocaine-Prilocaine ointment is applied to the incision margin every 8 hours for 48 hours

and analgesic effect will be determined by NRS.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences, Shaheed fahmideh Blvd., Hamadan, Iran

City

Hamadan

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 and Technology of Hamadan 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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Position

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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