Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of preoperative percutaneous electrical nerve stimulation on intensity of pain surgery in patient under inguinal herniorrhaphy in case and control groups

Protocol summary

Summary

This double-blind randomized clinical trial will be performed with the aim of evaluating the effect of percutaneous electrical nerve stimulation on post operative pain. Patients aged 20 to 50 with physical status of ASA I or II enter the study after obtaining the informed consent. Patients who have the conditions that prohibit the use of TENS device or who chronically use opioids or antidepressants will be excluded from the study. This study will be performed unicentrally on 66 men with inguinal hernia who underwent herniorrhaphy surgery with the Lichtenstein method. The patients are divided into two groups of case and control using the table of random numbers. TENS is performed on the patients one hour before the surgery. In the case group the TENS device is connected to the surgical incision site. In the placebo group the device is connected but there is no electrical stimulation. All the patients are evaluated for baseline pain sensitivity before the operation. In both groups after transition to the ward, analgesia will be established by the use of continuous infusion pump (PCA). The intensity of postoperative pain will be assessed by visual analog scale method at 2, 4, 6, 12 and 24 hours after the surgery. The amount of opioid analgesics, diclofenac and metoclopramide consumption is recorded. The above information along with demographic characteristics of the patients and duration of surgery are recorded in data forms and will be statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102311228N1**
Registration date: **2013-01-03, 1391/10/14**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-01-03, 1391/10/14

Registrant information

Name

Monir Janzamini

Name of organization / entity

Kashan 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, Kashan university of medical sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of preoperative percutaneous electrical nerve stimulation on intensity of pain surgery in patient under inguinal herniorrhaphy in case and control groups

Public title

Effect of preoperative percutaneous electrical nerve stimulation on severity of postoperative pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Male, aged 20 to 50, suffering from inguinal hernia; Use of Liechtenstein surgical procedure; Surgery performed in the morning to avoid circadian cycle; Physical status of ASA I or II; Absence of hearing, visual or talking impairment; Lack of cognitive impairment; No exclusion criteria Exclusion criteria: Conditions prohibiting the use of TENS, (such as pacemakers, because of the unknown effects of TENS on electrical conduction system or placing the electrode directly on open wounds); Obesity (weight more than 100 pounds above ideal weight); Recurrent, incarcerated and bilateral hernia; Skin infection or severe skin disease in the place of the electrodes; Chronic use of narcotics or antidepressant drugs

Age
From **20 years** old to **50 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

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
Kashan University of Medical Sciences ethics committee

Street address
Kashan Medical Sciences complex, Ghotbe Ravandi Blvd., Vice chancellor for research

City
Kashan

Postal code

Approval date
2012-11-20, 1391/08/30

Ethics committee reference number
3145/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R10.3

ICD-10 code description
Pain localized to other parts of lower abdomen

Primary outcomes

1

Description
The surgical site pain

Timepoint
2, 4, 6, 12 and 24 hours after the surgery

Method of measurement
Using the visual analog scale method

Secondary outcomes

1

Description
Vomitting

Timepoint
2, 4, 6, 12 and 24 hours after the surgery

Method of measurement
Asking the patient

2

Description
Nausea

Timepoint
2, 4, 6, 12 and 24 hours after the surgery

Method of measurement
Asking the patient

Intervention groups

1

Description
In the case group one hour before the surgery TENS device EV-906 model made in Taiwan is connected to the incision site by the interviewer number 1. Sensory intensity is activated in the range of 9 to 18 mA in the TENS device. Frequency and wavelength in each channel is increased until the patient is able to feel tingling without any unpleasant sensation. The prediction of postoperative pain is done by the interviewer number 2 using the Face Scale Test. In the operating room 2 micrograms per kilogram of fentanyl is prescribed as premedication. Anesthesia is induced with 6 milligrams per kilogram of Nesdonal. During the operation, two

micrograms per kilogram per hour fentanyl is prescribed as analgesic. After the surgery the patient will be monitored in the recovery room for 2 hours. During this time, if the patient's pain score based on Face-scale Test is over 4 IV infusion of 25 mg pethidine will be administered. After installation of the PCA pump which contains 200 mg pethedine dissolved in 100 cc normal saline the patient is transferred to the ward. If the button is pressed by the patient the amount of 1 cc of pethidine and normal saline solution is simultaneously injected. This dose can only be repeated for four times in an hour. If the patient's complaint of pain persists 100 mg diclofenac suppository is used. Questionnaire (containing questions about severity of pain, nausea, vomiting, headache and dizziness, and the amount of analgesic consumption) at 4, 6, 12 and 24 hours after the surgery is completed by asking the patient and evaluation of the PCA pump, and the patient's file.

Category

Treatment - Devices

2

Description

In the control group one hour before the surgery TENS device EV-906 model made in Taiwan is connected to the incision site by the interviewer number 1. The indicator light is on but the device is inactive. The prediction of postoperative pain is done by the interviewer number 2 using the Face Scale Test. In the operating room 2 micrograms per kilogram of fentanyl is prescribed as premedication. Anesthesia is induced with 6 milligrams per kilogram of Nesdonal. During the operation, two micrograms per kilogram per hour fentanyl is prescribed as analgesic. After the surgery the patient will be monitored in the recovery room for 2 hours. During this time, if the patient's pain score based on Face-scale Test is over 4 IV infusion of 25 mg pethidine will be administered. After installation of the PCA pump which contains 200 mg pethedine dissolved in 100 cc normal saline the patient is transferred to the ward. If the button is pressed by the patient the amount of 1 cc of pethidine and normal saline solution is simultaneously injected. This dose can only be repeated for four times in an hour. If the patient's complaint of pain persists 100 mg diclofenac suppository is used. Questionnaire (containing questions about severity of pain, nausea, vomiting, headache and dizziness, and the amount of analgesic consumption) at 4, 6, 12 and 24 hours after the surgery is completed by asking the patient and evaluation of the PCA pump, and the patient's file.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Vice Chancellor for research, Pezeshk Blvd., Ghotbe Ravandi Blvd.

City

Kashan

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, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Monir Janzamini

Position

General Surgery Assistant

Other areas of specialty/work

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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