Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Assessment the effect of TENS method on shoulder pain in women during gynecologic laparoscopic surgeries with spinal anesthesia in comparison with Fentanyl administration method

Protocol summary

Summary

This study is a single blind randomized clinical trial conducted in parallel and single-center in phase 2 of clinical trial. Patients between 18 and 50 years who are candidates for laparoscopic surgery in grade 1 and 2 are enrolled and patients over 120 kg and height of less than 140 cm are excluded from the study. We have a sample size of 80 patients who randomly are divided into two groups. Spinal anesthesia is performed in both groups. Before the surgery all patients receive a dose of 100 mg Diclofenac suppository. Then as soon complaining of pain by the patient in the treatment group with Fentanyl, dose of 50 mg intravenously is injected. In the TENS group, before undergoing spinal anesthesia four Pads of the device is adhered on scapula zone behind both shoulders with fixed frequency. Then spinal anesthesia is performed. Once patient complains of pain, the electrical impulse is applied up to 20 minutes. Then the patients state their pain levels by scoring the pain from number 0 to 10 at 0, 5, 10, 15 and 30 minutes after starting the intervention. In the absence of a favorable response to treatment in both groups, 5 minutes after intervention, extra dose of 50 mg Fentanyl is injected. In the end of trial, the amount of pain is compared in both groups.

General information

Acronym

transcutaneus electrical nerve stimulation

IRCT registration information

IRCT registration number: **IRCT2016031216765N3**
Registration date: **2016-05-13, 1395/02/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-13, 1395/02/24

Registrant information

Name

Zahra Tavoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2016-05-19, 1395/02/30

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of TENS method on shoulder pain in women during gynecologic laparoscopic surgeries with spinal anesthesia in comparison with Fentanyl administration method

Public title

Assessment the effect of transcutaneus electrical nerve stimulation method on shoulder pain in laparoscopic surgeries of women

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients with age between 18- 50 years old; laparoscopic surgeries of grade 1 and 2 Exclusion criteria: patients weighing over 120 kg; height less than 140 cm; disorders in cardiac rhythm; deformity or history of surgery in spinal cord; history of allergy to the drug of study; pregnancy; known contraindications of spinal anesthesia; malignancy
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization is performed by blocking.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Qods Street, Keshavarz Bulelvard
City
Tehran
Postal code
Approval date
2016-03-05, 1394/12/15
Ethics committee reference number
IR.TUMS.REC.1394.2139

Health conditions studied

1

Description of health condition studied
shoulder pain
ICD-10 code
R52.9
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
shoulder pain
Timepoint
0, 5, 10, 15 and 30 minutes after initiation of surgery and after surgery
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
the amount of extra analgesic drug administration
Timepoint
during surgery
Method of measurement
check list

Intervention groups

1

Description
Intervention group: Before spinal anesthesia 4 pads of the device with size of 4* 10 and at the distance of 5 cm is adhered in the zone of scapula and behind both shoulders and is regulated with frequency of 16 HZ and amplitude of 150 microseconds. After spinal anesthesia and administration of 100 mg Diclofenac suppository, surgery starts and as soon as complaining of shoulder pain by patient, TENS device is turned on for 20 minutes.
Category
Other

2

Description
Control group: After spinal anesthesia and administration of 100 mg Diclofenac suppository before surgery, as soon as patients states pain, Fentanyl with dose of 50 mg is injected IV.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women hospital

Full name of responsible person
Zahra Tavoli
Street address
Arash women hospital, Rashid street, Resalat highway, Tehranpars
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Science
Full name of responsible person
Dr Masoud Younesian
Street address
Qouds street, Keshavarz boulevard
City
Tehran
Grant name
Grant code / Reference number
31394
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Science
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
Tehran University of Medical Science, Arash women hospital
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Zahra Tavoli
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Person responsible for updating data

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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