

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

transcutaneous 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

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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 transcutaneous 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

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Arash women hospital, Rashid street, Resalat highway, Tehranpars

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Web page address**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

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Qouds street, Keshavarz boulevard

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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**

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Full name of responsible person

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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