Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of TENS (Transcutaneous Electrical Nerve Stimulation) for shoulder pain relief in patients after gynecologic laparoscopic surgery

Protocol summary

Study aim
The effect of TENS for shoulder pain relief in patients after gynecologic laparascopic surgery

Design
The present study is a randomized clinical trial study. In this study, 56 patients with informed consent were randomly assigned to each group underwent laparoscopic gynecology surgery. All of these patients underwent the same protocol of anesthesia according to entry criteria. Individuals are randomly assigned into two intervention and control groups. In the intervention group, two electrodes are placed vertically down the sides of the shoulders under the neck on the right and left side with the angle. The electrodes are inserted by the pain therapeutic group and used in the TENSE group twice a TENSE time and used for TENS for 20 minutes each time. In the control group, the device is not switched on. The study is done in parallel and double-blind so that the subjects and the analyst will not be aware of the allocation of the two groups.

Settings and conduct
This study is carried out at Rasoul-e-Akram Hospital in Tehran. Patients before the use of TENS and after using TENS by pain group anesthesiologist, patients at intervals of 2, 4, 8, 24 and 48 hours and then 72 hours after laparoscopy in terms of scour, shoulder pain, nausea, vomiting, recovery quality and the need for analgesia were evaluated. The study was double-blind so that the subjects and the analyst would not be aware of the allocation of the two groups.

Participants/Inclusion and exclusion criteria
Patients undergoing gynicologic laparoscopy are included in the study

Intervention groups
Intervention group: Patients undergoing laparoscopic surgery to reduce pain using TENS (Transcutaneous electrical nerve stimulation) Control group: Patients undergoing laparoscopic surgery without using TENS (Transcutaneous electrical nerve stimulation)

Main outcome variables
Pain score؛ Vomitting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150819023684N4**
Registration date: **2018-03-14, 1396/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-14, 1396/12/23**
Update count: **0**

Registration date
2018-03-14, 1396/12/23

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-02, 1396/12/11
Expected recruitment end date
2018-11-22, 1397/09/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of TENS (Transcutaneous Electrical Nerve Stimulation) for shoulder pain relief in patients after gynecologic laparoscopic surgery

Public title

The effect of TENS (Transcutaneous Electrical Nerve Stimulation) for shoulder pain relief in patients after gynecologic laparascopic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing gynecological laparoscopy Age 18 to 45 Lack of epilepsy No malignancy No DVT Lack of fragile and damaged skin in areas where TENS is used The lack of a pacemaker The lack of electronic implants The length of surgery is less than 3 hours Intra-abdominal pressure during laparacopy is not higher than 14 Absence of lesions and diaphragmatic diseases Lack of lung problems No SAS Depression Morbid obese patients Lack of addiction

Exclusion criteria:

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is simple, so that patients are randomly assigned to node A (intervention) and group B (control) after well-informed consent before surgery.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is done in two ways, so that subjects and statistical analyzers do not know the allocation of the two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

City

Tehran

Province

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-03-01, 1396/12/10

Ethics committee reference number

IR.IUMS.REC 1396.31054

Health conditions studied

1

Description of health condition studied

Shoulder pain after laparoscopy

ICD-10 code

U00-U85

ICD-10 code description

XXII Codes for special purposes

Primary outcomes

1

Description

Shoulder pain after laparoscopy based on VAS score

Timepoint

At intervals, 2, 4, 8, 24 and 48 hours, and then 72 hours after laparoscopy in terms of scores of shoulder pain

Method of measurement

VAS score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing gynecologic laparoscopic surgery to reduce pain using TENS (Transcutaneous electrical nerve stimulation)

Category

Treatment - Devices

2

Description
Control group: Patients undergoing gynecologic laparoscopic surgery without using TENS (Transcutaneous electrical nerve stimulation)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e-Akram Hospital, Maziar Mansouri St., Sattarkhan Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Shariati avenue, above the Roman bridge, Mousavand St., Karimi St., Alley Sabeti, ulat 78
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tasnim behboud arman company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available