

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 laparoscopic 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 gynecologic 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

Sepideh Khodaverdi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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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 laparoscopic 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

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

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

Full name of responsible person

Sepideh Khodaverdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tasnim behboud arman company

Full name of responsible person

Seyed Jafar Razavi Shirazi

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Shariati avenue, above the Roman bridge, Mousavand St., Karimi St., Alley Sabeti, ulat 78

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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

Iran University of Medical Sciences

Full name of responsible person

Sepideh Khodaverdi

Position

Professor Asistant

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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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