Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of transcutaneous electrical nerve stimulation on post elective cholecystectomy paincontrol

Protocol summary

Summary

The aim of this study is to evaluate the Efficacy of Transcutaneous Electrical Nerve Stimulation(TENS) as an analgesic treatment for patients undergoing open cholecystectomy.In this study that will take about a year after proposal registration;80 Patients 20 to 70 years old (men and women) who have been admitted for elective open cholecystectomy are selected after informed consent.Patients were randomly divided into two equal groups and Trancutaneous Electrical Nerve Stimulation(TENS) will be done 5 times for each patient.First dose will be performed immediately after surgery and Subsequent doses will be conducted every 12 hours until the third day after the operation during hospitalization. Same number of sessions will be done for Placebo group with [OFF] device.Pain assessment will be performed by visual analog scale each 12 hours until the third day and day5 & 7 after surgery by Phone call.Finally two groups will be compared after analyzing information.

General information

Acronym

Transcutaneous Electrical Nerve Stimulation(TENS)

IRCT registration information

IRCT registration number: **IRCT2015040421121N2**
Registration date: **2015-04-09, 1394/01/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-09, 1394/01/20

Registrant information

Name

Reza Movassaghi Gargari

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of transcutaneous electrical nerve stimulation on post elective cholecystectomy paincontrol

Public title

Effectiveness of transcutaneous electrical nerve stimulation on post cholecystectomy paincontrol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:All of Patients 20 to 70 years (men and women);Patients who have been admitted for elective open cholecystectomy. Exclusion criteria:Patients who did not consent to participate in the study;Patients who their wound is infected for any reason;Patients who have other medical problems in addition to cholecystectomy (ASA II-IV).

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Medical Ethics Commitee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Medicine Faculty, Medical Ethics Commitee

City

Tabriz

Postal code

5165665931

Approval date

2014-02-12, 1392/11/23

Ethics committee reference number

921192

Health conditions studied

1

Description of health condition studied

Patients who have been admitted for elective open cholecystectomy.

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

Primary outcomes

1

Description

Pain degree by VAS

Timepoint

Pain assessment will be performed by VAS Each 12 hours until third day and day5 & 7 after surgery by phone call

Method of measurement

According to visual analog scale

Secondary outcomes

1

Description

Painkillers and Opioid drugs Usage

Timepoint

Daily

Method of measurement

Depending on the dose in milligrams

Intervention groups

1

Description

After the surgery,the first group (control) which is consisted of 40 patients, in addition to conventional therapy such as intravenous and oral painkillers treat with the transcutaneus eiectrical nerve stimulation(TENS)device[OFF] (Placebo).Treatment rounds will be done 5 times for each patient.First time will be performed immediately after surgery and Subsequent times will be conducted every 12 hours until the third day after the operation during hospitalization.

Category

Other

2

Description

After the surgery,The second group (study) which is consisted of 40 patients, in addition to conventional therapy such as intravenous and oral painkillers treat with the transcutaneous electrical nerve stimulation (TENS)device[ON] also.Laser irradiation will be done 5 times for each patient.First dose will be performed immediately after surgery and Subsequent doses will be conducted every 12 hours until the third day after the operation during hospitalization.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research and Training Hospital

Full name of responsible person

Dr.Reza Movassaghi Gargari

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Tabriz University of Medical Sciences,Imam Reza Medical Research and Training Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Hasan Soleimanpour
Street address
Tabriz University of Medical Sciences,Medicine Faculty,Deputy of Research and Technology
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

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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