

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Transcutaneous 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3336 8740

###### Email address

movassaghir@tbzmed.ac.ir

###### 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 Committee of Tabriz University of  
Medical Sciences

###### **Street address**

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

###### **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 transcutaneous electrical 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

**Street address**

Tabriz University of Medical Sciences, Imam Reza  
Medical Research and Training Hospital

**City**

Tabriz

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Reza Movassaghi Gargari

**Position**

Assistant Professor of Department of Anesthesiology

**Other areas of specialty/work****Street address**

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rz\_movassaghi@yahoo.com

**Web page address****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****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Reza Movassaghi Gargari

**Position**

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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*