

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Using High Transcutaneous Electrical Nerve Stimulation (TENS) on the Severity of Pain, Nausea and Vomiting after Percutaneous Nephrolithotomy (PCNL)

Protocol summary

Summary

The purpose of this study is to examine the effect of using High Transcutaneous Electrical Nerve Stimulation (TENS) on the severity of pain, nausea and vomiting after percutaneous nephrolithotomy. In this study, 72 patients who underwent percutaneous nephrolithotomy in Ghaem Hospital, is being examined. This clinical trial, includes three groups and is single blinded. Inclusion criteria include: The patients who have 15-70 age old; All of consciousness patients who have unilateral percutaneous nephrolithotomy surgery. Exclusion criteria include: Those due to uncontrollable nausea and vomiting may require medication; The incidence of adverse events recorded in the patient during surgery; Drug addiction. Patients are randomly divided into three groups: control (24 peoples), intervention (24 peoples) and placebo (24 peoples). After surgery, in the intervention group TENS with a frequency of 100 Hz, based on patient tolerance at a distance of 5 cm from the nephrostomy for 20 minutes twice with an interval of six hours is established. In the placebo group TENS unit is turned on, but with zero intensity and frequency, i.e. no electrical stimulation. The severity of pain, nausea and vomiting before and after the intervention to be measured for 12 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112030989N1**
Registration date: **2017-01-25, 1395/11/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-25, 1395/11/06

Registrant information

Name

Radnoush Shadmehri

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 1300

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shadmehrir1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2016-10-31, 1395/08/10

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Using High Transcutaneous Electrical Nerve Stimulation (TENS) on the Severity of Pain, Nausea and Vomiting after Percutaneous Nephrolithotomy (PCNL)

Public title

The Effect of Using Transcutaneous Electrical Nerve Stimulation on the Severity of Pain, Nausea and Vomiting after Percutaneous Nephrolithotomy

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: The patients who have 15-70 age old; All of consciousness patients who have unilateral percutaneous nephrolithotomy surgery; Ability to speak and understand the Persian language. Exclusion criteria: Those due to uncontrollable nausea and vomiting may require medication; The incidence of adverse events recorded in the patient during surgery; Drug addiction; Being blind; The patients with motion sickness; Digestive disorders associated with nausea and vomiting; Mental retardation or mental disorders and epilepsy; Pregnancy; Patients who have cardiac pacemaker.

Age
 From **15 years** old to **70 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **72**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 In this study, the permutation block method is used and patients are divided into three groups: control, intervention and placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Department of Education, Sabzevar University of Medical Sciences, Tohid Shahr Blvd, Sabzevar

City

Sabzevar

Postal code

9613873136

Approval date

2016-10-15, 1395/07/24

Ethics committee reference number

IR.MEDSAB.REC.1395.78

Health conditions studied

1

Description of health condition studied

Surgery for kidney stones

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

pain

Timepoint

Before the intervention, immediately after intervention, 1, 2, 6 and 12 hours after intervention

Method of measurement

11-point Numeric Rating Scale

2

Description

Nausea

Timepoint

Before the intervention, immediately after intervention, 1, 2, 6 and 12 hours after intervention

Method of measurement

Visual Analog Scale

3

Description

Vomiting

Timepoint

After receiving TENS to 12 hours being counted.

Method of measurement

The vomiting and retching frequency form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgery, in the intervention group TENS with a frequency of 100 Hz, based on patient tolerance at a distance of 5 cm from the nephrostomy for 20 minutes twice with an interval of six hours is established. The severity of pain, nausea and vomiting before and after the intervention to be measured for 12 hours.

Category

Other

2

Description

In the placebo group TENS unit is turned on, but with zero intensity and frequency i.e. no electrical stimulation. The severity of pain, nausea and vomiting before and after the placebo TENS to be measured for 12 hours.

Category

Placebo

3

Description

In the control group, no intervention is applied. The severity of pain, nausea and vomiting before and after surgery to be measured for 12 hours.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Radnough Shadmehri

Street address

Ahmad Abad street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Mohammadzadeh

Street address

Department of research and technology, Building number one, next to the police station to SHahrout road, Sabzevar

City

Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Radnough Shadmehri

Position

MSc Student of Medical Surgical Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Hasan Khalili

Position

Faculty member of Medical Surgical Nursing group, MSc of Nursing

Other areas of specialty/work

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Person responsible for updating data

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Position

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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