Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 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
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Name of organization / entity
Sabzevar University of Medical Sciences
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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
Radnoush 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
Departman of research and technology, Building number one, next to the police station to SHahroud 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
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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