Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The Effect of using High Transcutaneous Electrical Nerve Stimulation on the severity of pain, nausea and vomiting after Percutaneous Nephrolithotomy

Protocol summary

Study aim

Determining the effect of transcutaneous electrical nerve stimulation (TENS) on frequency of pain, nausea and vomiting in patients after Percutaneous nephrolithotomy (PCNL)

Design

A clinical trial with a control and intervention group and a one-sided blind placebo randomized on 72 patients randomization by cube method

Settings and conduct

The environment of this research is the special clinical surgery department of Ghaem Hospital, this hospital is one of the centers It is an educational, research and therapeutic institution affiliated to Mashhad University of Medical Sciences. All surgeries in this Department by faculty professors and all PCNL surgeries by a specialist surgeon Endourology and laparoscopy are performed

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients aged 15 to 70 years. Patients undergoing unilateral PCNL surgery Exit criteria Occurrence of unwanted complications recorded in the patient's file during surgery and after.Receiving anti-nausea in recovery .pregnancy Any wounds, scratches and deformities in the areas where the electrodes are placed . Receiving narcotics and sedatives and anti-nausea drugs before the operation.

Intervention groups

. Then tens therapy for 20 minutes with a frequency of 100 Hz and the intensity of the current The patient's tolerance is established. Then immediately after turning off the device and in hours one and two the intensity of the pain And the severity of the patient's nausea is evaluated with a scale. After 6 hours, again after evaluating the intensity of pain and intensity Nausea, tennis therapy for 20 minutes with a frequency of 100 Hz and current intensity based on the patient's tolerance is established and then After the machine was turned off and at 7, 8, 12 and 18 hours, the pain and nausea were again severe is evaluated

Main outcome variables

Pain, severity of nausea, number of vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230316057732N1**
Registration date: **2023-05-30, 1402/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-30, 1402/03/09**
Update count: **0**

Registration date

2023-05-30, 1402/03/09

Registrant information

Name

Reza Saberani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3706 0439

Email address

dr.rsaber@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-06-22, 1402/04/01

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 on the severity of pain, nausea and vomiting after Percutaneous Nephrolithotomy

Public title

The Effect of using High Transcutaneous Electrical Nerve Stimulation on the severity of pain, nausea and vomiting after Percutaneous Nephrolithotomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to conduct the study Patients who are fully awake Patients aged 15 to 70 years Patients undergoing unilateral percutaneous kidney stone surgery Ability to understand and speak Persian

Exclusion criteria:

Using a different anesthesia protocol than other patients Receive anti-nausea in recovery movement disorder Having a digestive disease that causes vomiting and nausea Patients with mental retardation suffering from the mental illness or epilepsy Pregnancy Having cardiac arrhythmia and having a pacemaker Any wound and deformity at the place of placement of electrodes Diabetic neuropathy neuralgia History of use and familiarity with TENS Receiving narcotics or anti-nausea medication before surgery Addiction to drugs or opium Blindness or visual impairment

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

This is done when eligible patients are eligible to enter the study based on the form Entry and exit criteria of the study, by random allocation method and using the permutation block method in three groups Control, test and placebo were included. In the replacement block method, according to the sample size, blocks of 3 people with Three codes A, B, C were defined and considering all possible substitutions, finally 6 substitutions and 24 The block was obtained. Patients according to the time of entering the ward after the surgery is done by block method They were placed in one of the control, test or placebo groups. For example, in the first ABC block people based on the time of entering the ward after surgery in the test group and the second person in the placebo group and no The third was placed in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in research committee of medicine school of medical university of mashhad

Street address

Vakil abad Blvd medical university of mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913131

Approval date

2023-04-11, 1402/01/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.019

Health conditions studied

1

Description of health condition studied

Kidney stones

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

2

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

3

Description of health condition studied

Pain

ICD-10 code

R52

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain reduction
Timepoint
Before tens, immediately after the intervention of the first tens, the first hour after that, the second hour, the sixth hour, immediately after the second tens, the seventh hour, the eighth hour, the twelfth hour, the eighteenth hour
Method of measurement
Visual analogue scale

2

Description
Severity of nausea
Timepoint
Before tens, immediately after the intervention of the first tens, the first hour after that, the second hour, the sixth hour, immediately after the second tens, the seventh hour, the eighth hour, the twelfth hour, the eighteenth hou
Method of measurement
Visual analogue scale

3

Description
Number of Vomiting
Timepoint
Within 18 hours after surgery
Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High Transcutaneous Electrical Nerve Stimulation In such a way that when admitting the patient in the ward, immediately after the patient's statement of pain, the intensity of pain and the intensity of nausea are evaluated and recorded using the relevant criteria. Then, the patient's skin at the location of the electrodes is cleaned with cotton dipped in alcohol and warm water for any secretions and grease, after that the electrodes are covered with disposable wet pads with a double layer with a one-sided layer covered with leather to prevent loss. The current of the device is connected to a distance of 5 cm from the area of nephrostomy of the kidney undergoing surgery. Tens therapy was established for 20 minutes with a frequency of 100 Hz and the intensity of the current was based on the patient's tolerance. Then, immediately after turning off the device and at one and two hours, the severity of the patient's nausea is evaluated with a scaleAfter 6 hours, again after evaluating the intensity of pain and intensity of nausea, tennis therapy is established for 20 minutes with frequency of 100 Hz and intensity of current according to the patient's tolerance, and after turning off the device and at 7th, 8th, 12th and 18th hours, the intensity is again increased. Pain and severity of nausea are evaluated
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Reza saberani
Street address
No 135 baharestan 5 north khayam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid ghayour mobarhan
Street address
Daneshgah street ghoreyshi bulding floor 3
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Razavi Khorasan
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9138813944
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Fax
+98 51 3843 0249
Email
vcresraech@mums.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Reza Saberani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Urology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
All person

Under which criteria data/document could be used

All researchers can perform the required analyzes under the condition of observing research ethics

From where data/document is obtainable

Reza saberani dr.rsaber@gmail.com

What processes are involved for a request to access data/document

After sending the request by email to the responsible author Reza Sabrani

Comments