Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on pain intensity during insertion of spinal needle and time of anesthesia in patients under spinal anesthesia

Protocol summary

Summary

Objectives: The purpose of this study is to examine the effects of Transcutaneous Electrical Nerve Stimulation on the severity of pain during insertion of spinal needle and time of anesthesia in patients under spinal anesthesia. This study is a clinical trial, double blind with randomization by Closed envelop that 60 patients will be divided in two groups: intervention and placebo. Inclusion criteria include: The patients who have 20 to 40 years old; weight of patients less than 100 kg; Ability to speak and understand the Persian language. Exclusion criteria include:The redness and burning sensation at the site of electrode; the incidence of cardiac arrhythmia. TENS electrodes are placed above and below the spinal needle of entrance area. In the intervention group, the TENS is set with 60 Hz and in the placebo group, TENS is inactive. Immediately after entering the spinal needle, pain intensity measured by VAS scale in two groups. Frequency changes to 10 Hz in the intervention group and continues until the end of surgery. Numbness and immobility duration is compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032727819N3**
Registration date: **2017-05-19, 1396/02/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-05-19, 1396/02/29

Registrant information

Name

Rasool Kawyan Nejad

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice– Chancellery of Research & Technology Affairs of Kermanshah University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on pain intensity during insertion of spinal needle and time of anesthesia in patients under spinal anesthesia

Public title

Effect of Transcutaneous Electrical Nerve Stimulation on pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non-use of analgesic and sedative drug

before surgery; The patient's ability to understand the pain score and answer questions; weight of patients less than 100 kg; age 20 to 40 years old; no pregnancy. Exclusion criteria: pain in other areas; history of dangerous arrhythmia and pacemaker; a skin problem at the site of the electrodes; injection analgesic and sedation drugs during spinal anesthesia.

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Closed envelop will be used for randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences

Street address
Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City
Kermanshah

Postal code
6715847141

Approval date
2017-03-08, 1395/12/18

Ethics committee reference number
IR.kums.REC.1395.762

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52

ICD-10 code description
Pain, not elsewhere classified

2

Description of health condition studied
Immobility

ICD-10 code
R26.3

ICD-10 code description
Immobility

3

Description of health condition studied
Numbness

ICD-10 code
R20.2

ICD-10 code description
Numbness of skin

Primary outcomes

1

Description
Pain after spinal needle insertion

Timepoint
Immediately after entering the spinal needle

Method of measurement
VAS scale

2

Description
The duration of anesthesia

Timepoint
Until the time of return of lower extremity sense

Method of measurement
The duration of anesthesia is measured in minutes

3

Description
The duration of immobility

Timepoint
Until the time of return of lower extremity mobility

Method of measurement
Immobility time is measured in minutes

Secondary outcomes

empty

Intervention groups

1

Description
The duration of anesthesia is measured in minutes
Intervention group: TENS electrodes are placed on areas of up and down needle insertion. TENS frequency of 60

Hz is set and then changes to 10 Hz.

Category

Treatment - Devices

2

Description

Placebo group: TENS electrodes are placed on areas of up and down needle insertion. TENS is inactive.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza of Hospital

Full name of responsible person

Javad Aminisanam

Street address

Emam Reza of Hospital, Bagh e Abrisham

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behroz Hamze

Street address

Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

City

Kermanshah

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, Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Rasool Kaviannezhad

Position

faculty member

Other areas of specialty/work

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Person responsible for updating data

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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