

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

• Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation in Control the pain intensity of postoperative Orthopedic patients

Protocol summary

Study aim

The aim of this study is to determine the effectiveness of various types of Transcutaneous Electrical Nerve Stimulation on the severity of postoperative pain in orthopedic patients

Design

In this research, 50 eligible patients referring to Khatam Hospital of Zahedan were chosen purposefully and a envelope was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This single-step non-blinded clinical trial was done on 160 patients with orthopedic surgeries at Khatam Hospital of Zahedan.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Over 18 years of age; Not having pacemakers and dangerous arrhythmia during a clinical trial; Not taking narcotic drugs 6 hours before the intervention; 24 hours past the surgery. Exclusion criteria include: Intolerance to the device

Intervention groups

The study in four groups of: control with 40 subjects, The control group received routine care. The intervention group was affected by TENS method for 30 minutes; The High group with a frequency of 100 Hz and an intensity of 10-30 MA; Low group at a frequency of 10 Hz, and an intensity of 20-50 MA, and in the burst group 1-2 set of electric pulses with a frequency of 100 Hz and low intensity are applied on the patient, expressing pain.

Main outcome variables

En Pain as an unpleasant psychosomatic experience has been always a challenge for health care providers. Nurse are the essential pillars for assessing and managing pain. In this study, we evaluate pain control in orthopedic patients by non-pharmacological methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036612N2**

Registration date: **2017-12-01, 1396/09/10**

Registration timing: **prospective**

Last update: **2017-12-01, 1396/09/10**

Update count: **0**

Registration date

2017-12-01, 1396/09/10

Registrant information

Name

Simin Sharifi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+54 33442481

Email address

sharifi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

- Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation in Control the pain intensity of postoperative Orthopedic patients

Public title

"Effect of Transcutaneous Electrical Nerve Stimulation in pain controlling Orthopedic Patients"

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

All orthopedic patients more than 18 years old, who have pain after orthopedic surgery

Exclusion criteria:

Having a pacemaker and Cardiac arrhythmia pregnant women

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomized study method is simple random. The method will be used to refer to the orthopedic section of the available samples.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Zahedan University of Medical Sciences

Street address

Ganat Blvd , Zahedan _ Iran, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.ZAUMS.REC.1396;151

Health conditions studied**1****Description of health condition studied**

The Relationship of Effect of Nervous-Stimulated Nervous Stimulation on the Control of Post-Operative Orthopedic Patients' Pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

Before intervention immediately after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: The HIGH TENS group in this group uses the Total TENS EMS 2015 to set the frequency to 100 Hz and intensity of 10-30 MA. For each person only once, for 30 minutes. To stimulate, place the device's electrodes 10 cm on both sides of the lesion.

Category

Other

2**Description**

Intervention group 2: The LOW TENS group in this group uses the Total TENS EMS 2015 device to set the frequency to 10 Hz and the intensity of 50-20 mA. For each person only once, for 30 minutes. To stimulate, place the device's electrodes 10 cm on both sides of the lesion.

Category

Other

3**Description**

Intervention group 3 : The BURST group in this group uses the Total TENS EMS 2015 device to set the settings to 1_2 pulse circuits with a frequency of 100 Hz and low current. For each person only once, for 30 minutes. To stimulate, place the device's electrodes 10 cm on both sides of the lesion.

Category

Other

4

Description

Control group: routine care is provided to control patient's pain

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Hospital in Zahedan

Full name of responsible person

Motahareh Farshad Faghih

Street address

Zahedan_ Jame Jam blv, Khatam Hospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815733169

Phone

+98 54 3322 0501

Email

Motahareh_farshadfaghih@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Noor Mohamad Bakhshay

Street address

Ganat Blvd , Zahedan _ Iran, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5744

Email

nmbakhsha@zdmv.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Motahareh Farshad Faghih

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 20, Mirzadeh Dead End, Emam Khomeini st, Rasht_Iran

City

Rasht

Province

Guilan

Postal code

4137616579

Phone

+98 31 3332 8590

Fax

Email

motahareh_farshadfaghih@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Simin Sharifi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Behdasht blv, Zahedan Faculty of Nursing and
Midwifery
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 543425765
Fax
Email
siminsharifi1@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Motahareh Farshad Faghih
Position
Nursing Graduate Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 20, Mirzadeh Dead End, Emam Khomeini st,
Rasht_Iran
City
Rasht

Province
Guilan
Postal code
4137616579
Phone
+98 31 3332 8590
Fax
Email
motahareh_farshadfaghih@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available