

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

comparison the effects of high-frequency, low frequency and placebo transcutaneous electrical nerve stimulation (TENS) on the brain electrical activities following induced pain in healthy subjects

Protocol summary

Summary

The purpose of this study is to compare the effects of transcutaneous electrical nerve stimulation (TENS) with high-frequency, low frequency and placebo on the brain electrical activities following induced pain in healthy subjects. In the present study, 30 right handed healthy subjects (10 subjects in each group) aged 25-18 years are selected through convenience sampling and then are assigned to three TENS groups (high frequency, low frequency, placebo) randomly. First, the brain waves are recorded for 2 minutes (1 minute with open eyes, 1 minute with close eyes). Then, by Submaximal Effort Tourniquet Technique ischemic pain is induced in the left forearm and hand and the subject records pain intensity by Visual Analog Scale (VAS), brain waves are recorded for 2 minutes and one type of TENS is applied for 20 minutes. After that, TENS is turned off and VAS and brain waves are recorded immediately, 15 and 30 minutes after the TENS. Finally, the effect of three types of mentioned TENS on the power of brain waves will be compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501191552N3**

Registration date: **2015-02-18, 1393/11/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-18, 1393/11/29

Registrant information

Name

Maryam Ebrahimian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Shiraz University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the effects of high-frequency, low frequency and placebo transcutaneous electrical nerve stimulation (TENS) on the brain electrical activities following induced pain in healthy subjects

Public title

Comparison of the Effects of Three Types of Electrical Stimulation on Brain Activity Following Induced Pain in Healthy Subjects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Right-handed healthy subjects between the ages of 18-25 Exclusion criteria: Presence of any pain; cardiovascular diseases; neuromuscular diseases; use of antidepressants and antihistamines drugs and alcohol; deformity of the upper limb (especially the hand)

Age

From **75 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

in front of Felestin St., Zand Ave.

City

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1433671348

Approval date

2014-12-30, 1393/10/09

Ethics committee reference number

CT- 9372-7272

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Power of brain waves

Timepoint

Before, immediately after, 15 and 30 minutes after intervention

Method of measurement

Electroencephalography

2

Description

Pain intensity

Timepoint

Immediately after, 15 and 30 minutes after intervention

Method of measurement

Visual Analog Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group No.1, the high frequency TENS(80 HZ) with 150 microsecond duration for 20 minutes will be used.

Category

Treatment - Other

2

Description

In the intervention group No.2, the low frequency TENS(3 HZ) with 250 microsecond duration for 20 minutes will be used.

Category

Treatment - Other

3

Description

In the control group, the placebo(sham) TENS for 20 minutes will be used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Sciences School of Shiraz University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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University of Medical Sciences
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7th floor of Central Building of Shiraz University of
Medical Sciences, In front of Felestin Street, Zand
Avenue.
City
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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 Affairs of Shiraz 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