Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effects of sensory electrical stimulation on postural control in diabetic neuropathy patients

Protocol summary

Summary

The primary aim of this study is to investigate the possible effect of TENS on postural control in patients with diabetic neuropathy. Twenty eight patients participate in this study. Then, patients by using block randomization allocate in intervention and control group. The inclusion criteria are patients with diabetic neuropathy age 40-55 years old with score 7 or above 7 in mishigan questionnaire.The exclusion criteria are the history of lower limb surgery, muscluskeletal and neuromuscular disorder. All participants are recruited from referrals of Motahari diabet clinic in Shiraz. We performeTENS for both groups. Intervention group are positioned supine on a treatment bench; then,high frequency electrical stimulation with the duration of 250 µs and 100 HZ frequency through surface electrodes placed at both sides of knee bilaterally for 4 minutes at sensory level. In control group, protocol are done like to intervention group but they receive sham electrical stimulation. postural control assess befoe, immediately and 15 and 30 minute after of the TENS application. we expect that TENS improve postural control in diabetic neuropathic patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304062391N10**
Registration date: **2014-07-18, 1393/04/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-18, 1393/04/27

Registrant information

Name

Zahra Rojhani Shirazi

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 1552

Email address

rojhaniz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rehabilitation Faculty- Shiraz Univercity of Medical Science

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2014-01-01, 1392/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of sensory electrical stimulation on postural control in diabetic neuropathy patients

Public title

Effects of electrical stimulation on postural control

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: diabetic neuropathic patient 40-55 years old; Michigan Neuropathy Screening Instrument (MNSI) patient questionnaire 7 or above 7; MNSI above 2
exclusion criteria:fracture; dislocation; soft tissue injuries

in lower extremities in 6 month ago; history of surgery in lower extremities; ankle or knee pain in test day; muscoloskletal and neuromuscular disorder like RA and myopathy; knee flexion contracture; use of walking aids;inner ear and vestibular system problems; regular exerciseing

Age
From **40 years** old to **55 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **28**

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 Science

Street address
School of Rehabilitation Sciences, Chamran Boulevard, Abiverdi Street

City
Shiraz

Postal code

Approval date
2013-03-13, 1391/12/23

Ethics committee reference number
91/436616

2

Ethics committee

Name of ethics committee
Shiraz Univercity of Medical Science

Street address
Chamran Boulevard, Abiverdi Street

City
Shiraz

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
91/436616

Health conditions studied

1

Description of health condition studied
Diabetic Polyneuropathy

ICD-10 code
G63.2

ICD-10 code description
Diabetic Polyneuropathy

Primary outcomes

1

Description
Balance

Timepoint
Immediately after interventio,15 and 30 min after interventio

Method of measurement
By forcplate

2

Description
Balance

Timepoint
Immediately, after 15 and 30 min of stimulation using

Method of measurement
Force plate

Secondary outcomes

empty

Intervention groups

1

Description
high frequency electrical stimulation(high frequency TENS with the duration of 250 µs and 100 HZ frequency) Intervention group are positioned supine on a treatment bench; then, electrical stimulation applies via an surface electrical stimulations places through surface electrodes placed at both side of knee bilaterally for 4 minutes at sensory level.

Category
N/A

2

Description
high frequency electrical stimulation(high frequency TENS with the duration of 250 µs and 100 HZ frequency) control group are positioned supine on a treatment bench; then,sham electrical stimulation applies via an surface electrical stimulations places through surface

electrodes placed at both side of knee bilaterally for 4 minutes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahari Diabetes Clinic

Full name of responsible person
Zahra Rojhani Shirazi

Street address
Faculty of Rehabilitation Sciences,Chamran Boulevard, Abiverdi Street

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz Univercity of Medical Sciences

Full name of responsible person
Gholamreza Hatam

Street address
Shiraz University of Medical Sciences, Shiraz, Fars

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz Univercity 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
Shiraz Univercity of Medical Sience

Full name of responsible person
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Position
Asistant Professor

Other areas of specialty/work

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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