

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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, musculoskeletal and neuromuscular disorder. All participants are recruited from referrals of Mottahari 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 μ s 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 before, 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 University 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; musculoskeletal and neuromuscular disorder like RA and myopathy; knee flexion contracture; use of walking aids; inner ear and vestibular system problems; regular exercising

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 University 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 μ s 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 μ s 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

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University 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 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

Shiraz University of Medical Science

Full name of responsible person

Dr. Zahra Rojhani Shirazi

Position

Assistant Professor

Other areas of specialty/work

Street address

Chamran Boulevard, Abiverdi 1 Street

City

Shiraz

Postal code

Phone

+98 71 1627 1551

Fax

Email

rojhaniz@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr. Zahra Rojhani Shirazi

Position

Assistant Professor

Other areas of specialty/work

Street address

Chamran Boulevard, Abiverdi 1 Street

City

Shiraz

Postal code

Phone

+98 71 1627 1551

Fax

Email

rojhaniz@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rojhani Shirazi

Position

PHD

Other areas of specialty/work

Street address

School of Rehabilitation Sciences, Chamran Boulevard,
Abiverdi Street

City

Shiraz

Postal code

Phone

+98 71 1627 1552

Fax

+98 71 1627 2495

Email

rojhaniz@sums.ac.ir

Web page address

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