Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of ten sessions balance training on balance in diabetic neuropathy patient.

Protocol summary

Summary

Peripheral neuropathy is a common complaint of diabetes. Peripheral neural damage in turn will cause balance impairments in diabetic patients. Diabetic neuropathy plays a significant role in falling among elderly patients, people with peripheral neuropathy caused by diabetes often experience balance disorder. Postural sway in these patients is increased, especially with the eyes closed .Peripheral neuropathy caused by diabetes causes significantly impaired sensation in the feet, reducing patients' ability to control their balance properly during daily activities. Poor balance can be due to proprioception impairment. Balance problems are also caused by movement-strategy impairment, biomechanical structural disorders, and disorientation. 34 patient with moderate to severe neuropathy (toronto scale>8) that confirmed with electrodiagnosis are divided accidently into two group. All patient are examined for balance index with biodex balance system and berg balance scale questionnaire and then received physical therapy with IR and TENS for 30 minute 3 time in week. Intervention consists of 20 minute balance training with biodex balance system in ten sessions for 20 minute every session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211214641N6**
Registration date: **2012-12-05, 1391/09/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-12-05, 1391/09/15

Registrant information

Name
Bina Eftekharsadat
Name of organization / entity
Tabriz university of medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1330 3193
Email address
binasadat@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

physical medicine and rehabilitation research center

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ten sessions balance training on balance in diabetic neuropathy patient.

Public title

Effect of ten sessions balance training on balance in diabetic neuropathy patient.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 50 to70; confirmed diabetes type 2; moderate or severe diabetic neuropathy in toronto scale; peripheral neuropathy which confirmed with electrodiagnostic tests; the ability to stand

independently, BMI less than 30. Exclusion criteria: diabetic ulcer; infection or partial amputation in feet; inability to stand independently; other diseases affecting balance; neurologic or orthopedic problem affecting balance; History of repeated ankle sprains in the year prior to the study; severe pain influencing balance; visual problems inability to see the stabilometer cursor; severe pain interfere with balance.

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tabriz university of medical sciences

Street address
Golgasht Avenue

City
Tabriz

Postal code

Approval date
2012-10-29, 1391/08/08

Ethics committee reference number
91140

Health conditions studied

1

Description of health condition studied
Endocrine, nutritional and metabolic diseases

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
change in balance index with biodex balance system

Timepoint
before and after training

Method of measurement
Balance idex with biodex system

Secondary outcomes

1

Description
functional balance

Timepoint
befor and after training

Method of measurement
Berg balance scale

Intervention groups

1

Description
control :physical therapy(IR and TENS)

Category
Rehabilitation

2

Description
intervention: 10 session balance training with biodex balance system with physical therapy(IR and TENS)

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
Mis Poorahmadian

Street address
Physical medicine and rehabilitation research center, Emam Reza hospital

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Physical medicine and rehabilitation research center
Full name of responsible person
Dr. Seyed Kazem Shakouri
Street address
Emam Reza Hospital, Golgasht avenue
City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Physical medicine and rehabilitation research center

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
Tabriz university of medical sciences
Full name of responsible person
Dr. Bina Eftekharsadat
Position
Associated professor-Physiatrist
Other areas of specialty/work
Street address
Tabriz university of medical sciences, Golgasht avenue
City
Tabriz
Postal code
Phone
+98 41 1336 1928
Fax
Email
binasadat@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz university of medical sciences
Full name of responsible person
Dr. Bina Eftekharsadat
Position
Associated professor-Physiatrist
Other areas of specialty/work
Street address
Tabriz university of medical sciences, Golgasht st
City
Tabriz
Postal code
Phone
+98 41 1336 1928
Fax
Email
binasadat@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Roghaye Azizi
Position
Physical medicine and rehabilitation resident
Other areas of specialty/work
Street address
City
Tabriz
Postal code
Phone
Fax
Email
azizidr@ymail.com
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