Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Multi-Centre, Randomised, Double-Blind, Placebo Controlled Trial of the Effect of Neurotec in Symptomatic Diabetic Neuropathy

Protocol summary

Summary

The purpose of this multicentre randomized double-blind placebo controlled phase III trial is to determine the therapeutic effect of Neurotec, a novel herbal drug made by ParsRoos Companyin Iran, in symptomatic diabetic neuropathy. 300 patients with past history of at least 1 year symptomatic diabetic neuropathy will be assigned to one of the following treatment groups through a permuted block randomization method. Group 1 will receive 120 mg (1 capsule) Neurotec two times a day, group 2 will receive Gabapentin 300 mg (1 capsule) two times a day and group 3 will receive placebo (1 identical capsules as active drugs three times a day) for 4 months and 1 capsule a day for another two-month period. Patients will be followed for three months after completion of treatment period. Follow-up visits will be done every other week by a general physician and every month by a Physiatrist or Neurologist. The primary outcome measures of the study are pain and severity of symptoms measured using Neuropathy Symptom Score (NSS). The other outcomes are quality of life, Michigan Neuropathy Score Scale, nerve conduction velocity (NCV), monofilament test, clinician and patient's global impression of change.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802201044N3**
Registration date: **2009-10-10, 1388/07/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-10-10, 1388/07/18

Registrant information

Name
Pezhman Madani
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 8822 0088
Email address
pezhman@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

ParsRoos Company

Expected recruitment start date

2009-10-10, 1388/07/18

Expected recruitment end date

2010-10-10, 1389/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Multi-Centre, Randomised, Double-Blind, Placebo Controlled Trial of the Effect of Neurotec in Symptomatic Diabetic Neuropathy

Public title

Neurotec in Symptomatic Diabetic Neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Pain equivalent to 4 or more on a numerical scale between 0 and 10, Diagnosis of Diabetes Mellitus (Type 1 or 2) defined by American Diabetes Association criteria for at least 3 years, Haemoglobin A1C

less than 10%, History of Diabetic Neuropathy for more than a year, Age more than 18 years and less than 60, diagnosis of neuropathy based on Michigan Neuropathy Screening Instrument Exclusion Criteria: Presence of uncontrolled or poor controlled DM, Presence of neuropathy due to other causes than DM, Receiving any investigational drug within 30 days prior to screening, Presence of active or infected diabetic wound, Amputation, Presence of any other systemic or chronic diseases such as: Myopathy, Vasculitis, Peripheral Vascular Diseases, Chronic hepatic or renal diseases, clinically complicating pulmonary, Cardiac, Hematologic, Gastrointestinal, Endocrine disease or Malignancy, Symptomatic degenerative joint disease, active radiculopathy or discopathy, spinal stenosis , active degenerative disc diseases, chronic sciatalgia, sacroiliac joint dysfunction or any chronic painful condition involving lower extremities, apparent or diagnosed psychological problem such as anxiety or depression, Diabetic Retinopathy or retinal haemorrhage, Pregnancy or intention of becoming pregnant during the study period (9 months), Inability to give informed consent according to the agreed process, Corticosteroid therapy, Any drug hypersensitivity, Radiotherapy, Chemotherapy or any immuosuppressive drug use, Electrolyte imbalance

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Endocrinology and Metabolism Research Centre

Street address
Fifth floor, Shariati hospital, North Kargar Ave., Tehran, Iran

City
Tehran

Postal code
14114

Approval date
empty

Ethics committee reference number
E-0062

Health conditions studied

1

Description of health condition studied
Diabetic Neuropathy

ICD-10 code
G63.2

ICD-10 code description
Diabetic polyneuropathy

Primary outcomes

1

Description
Pain

Timepoint
Baseline, every other week during treatment period (6 months) and every month during follow-up period (3 months)

Method of measurement
pain during the last 2 weeks prior to study visits through a Visual Alalogue Scale recorded daily by the patients in diary notebook

2

Description
Severity of neuropathy

Timepoint
Baseline, every other week during treatment period (6 months) and every month during follow-up period (3 months)

Method of measurement
Neuropathy symptom score

Secondary outcomes

1

Description
Nurve Conduction Velocity

Timepoint
Baseline, weeks 24 and 36

Method of measurement
Conduction velocity of tibial, proneal and sureal nerves

2

Description
Monofilament test

Timepoint
Baseline, weeks 8, 16, 24 and 36
Method of measurement
Monofilament test

3

Description
Existence and severity of peripheral neuropathy
Timepoint
Baseline, weeks 8, 16, 24 and 36
Method of measurement
Michigan Neuropathy Score

4

Description
Patient's Global Impression of Change (PGIC)
Timepoint
Baseline, every other week during treatment period and every month during follow-up period
Method of measurement
10-point rating scale from very poor condition (1) to very good (10)

5

Description
Quality of life
Timepoint
Baseline, weeks 16, 24 and 36
Method of measurement
SF-12 questionnaire

6

Description
Clinical Global Impression of Change (CGIC)
Timepoint
Baseline, every other week during treatment period and every month during follow-up period
Method of measurement
10-point rating scale from very poor condition (1) to very good (10) determined by the physician

Intervention groups

1

Description
Neurotec 120 mg (1 capsule) two times a day for 4 months and then 120 mg, 1 capsule a day for two month
Category
Treatment - Drugs

2

Description
Gabapentin 300 mg (1 capsule) two times a day for 4 months and then 300 mg, 1 capsule a day for 2 months
Category
Treatment - Drugs

3

Description
Placebo 1 identical capsule as active drug two times a day for 4 months and then 1 capsule a day for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Research Center, Tehram University of Medical Sciences
Full name of responsible person
Dr Pezhman Madani
Street address
Shariati Hospital, North Kargar Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
ParsRoos Company
Full name of responsible person
Seyyed Hesamoddin Madani
Street address
No. 568,13th alley, Hormozan st., Sahrak-e-Ghods, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
ParsRoos Company
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
Endocrine and Metabolism research Center, Tehran University of Medical Sciences

Full name of responsible person
Pezhman Madani
Position
Physiatrist, Assistant Professor
Other areas of specialty/work
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Shariati Hospital, North Kargar Ave.
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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