

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Company in 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)

Phone

+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 Analogue 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**

Nerve 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,
Tehran 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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Endocrine and Metabolism Research center, Tehran
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Physiatrist, Assistant Professor

Other areas of specialty/work

Street address

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