

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Safety and efficacy of oral form of Neurotec in reduction of pain in patients with diabetic neuropathy, A phase II clinical trial

Protocol summary

Summary

This is a phase II, single armed, trial of Safety and Efficacy of Neurotec, a herbal extract. After signing a consent form 14 patients will be recruited into this trial during which they will receive oral capsules of Neurotec twice a day for 12 weeks and once a day for another 4 weeks. Every 2 weeks a detailed clinical and laboratory examination will be carried out. This will continue up to 24 weeks. Primary outcome measure is pain which will be measured on 2 week intervals. Secondary outcome measures are Michigan and UK diabetic neuropathy score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138705221044N1**

Registration date: **2008-09-05, 1387/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-09-05, 1387/06/15

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

Pars Roos Company, Tehran, Iran

Expected recruitment start date

2008-08-01, 1387/05/11

Expected recruitment end date

2008-08-10, 1387/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of oral form of Neurotec in reduction of pain in patients with diabetic neuropathy, A phase II clinical trial

Public title

Safety and efficacy of oral form of Neurotec in reduction of pain in patients with diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having diabetic I or II having pain and paresthesia interfering with every day activities
Diminished ankle reflex Abnormal 128 Hz vibration test
Exclusion criteria: Unwilling to sign a written consent
Non-diabetic neuropathy Wound infection or infection in extremities ischaemic heart disease Heart failure receiving immunosuppressive drugs, corticosteroids, chemotherapy, radiotherapy Alcohol and substance misuse Electrolyte disturbances History of known hypersensitivity to drugs Haemodialysis

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 14

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

ANZCTR

Secondary trial Id

ACTRN12608000388314

Registration date

2008-04-08, 1387/01/20

Ethics committees

1

Ethics committee

Name of ethics committee

Endocrine and Metablism research Centre Ethic committee

Street address

5th Floor, Shariati Hospital, North Karegar street, Tehran, Iran

City

Tehran

Postal code

14114

Approval date

empty

Ethics committee reference number

E-0005

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain measured by Visual Analogos Scale(VAS)

Timepoint

baseline, 2, 4, 8, 12, 16 and 24 weeks

Method of measurement

measured by Visual Analogos Scale(VAS)

Secondary outcomes

1

Description

Michigan Diabetic Neuropathy score

Timepoint

baseline, 2, 4, 8, 12, 16 and 24 weeks

Method of measurement

Questionnaire

2

Description

UK Diabetic Neuropathy score

Timepoint

baseline, 2, 4, 8, 12, 16 and 24 weeks

Method of measurement

Questionnaire

3

Description

Semmes-Weinstein monofilament test for peripheral sensory neuropathy

Timepoint

baseline, 2, 4, 8, 12, 16 and 24 weeks

Method of measurement

Monofilament test

Intervention groups

1

Description

Oral form of drug Neurotec 120 mg capsules, 2 capsules a day for 16 weeks and 1 capsule a day for another 8 weeks

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and Metablism research Centre

Full name of responsible person

Dr.Pezhman madani

Street address

5th Floor, Shariati Hospital, North Karegar street, Tehran, Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrine and Metablism research Centre

Full name of responsible person

Ramin Heshmat

Street address

5th Floor, Shariati Hospital, North Karegar street,
Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrine and Metablism research Centre

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

EMRC

Full name of responsible person

Ramin Heshmat

Position

Epidemiologist

Other areas of specialty/work

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pezhman madani

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Medical physics and rahbilitation specialist

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work

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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