

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The comparison of duloxetine and pregabalin effects on plasma concentration of nitric oxide (NO) and inducible nitric oxide synthase (iNOS) in type 2 diabetic patients and the role of these mediators in neuropathic pain

Protocol summary

Summary

Objectives: The aims of this study are to compare the effects of Duloxetine and Pregabalin on plasma concentration of NO and iNOS in painful neuropathic patients with type 2 diabetes and to evaluate the relation of plasma concentration of No and iNos with patients neuropathic pain severity. Design and setting: We will randomly select 60 patients with considering some inclusion and exclusion criteria and then we will divide them to two equal number groups. The study will be single blind. Plasma concentration of No and iNos will be compared before and after administration of Duloxetine and Pregabalin. Correlation between No and iNOS plasma concentration and neuropathic pain will also be evaluated. Major eligibility criteria: Type 2 diabetic patients, 40-60 years old, both genders, having at least 4 score diabetic neuropathic pain by Visual Analogue Scale (VAS), having healthy liver and kidney performance and not having any other neuropathy Interventions: one of groups will receive placebo of Duloxetine 30 mg capsules once daily and the other group will receive placebo of Pregabalin 75 mg capsules twice daily for ten days before drugs beginning, afterward, the first group will receive Duloxetine 30 mg once daily for one week and then 60 mg once daily for seven more weeks. The second group will receive Pregabalin 75 mg twice daily for one week, afterward, 150 mg twice daily for seven more weeks. we will collect patients blood samples before drugs administration and day 30 and day 60 after drugs taking. Variables: Finally we will assay NO and iNOS concentration of blood samples by means of ELISA kits. We will evaluate pain severity of patients weekly by VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012932277N1**

Registration date: **2017-07-19, 1396/04/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-19, 1396/04/28

Registrant information

Name

Moosareza Memari

Name of organization / entity

Pharmacology Department, School of Medicine,
Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2387 2539

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Recruitment status

Recruitment complete

Funding source

The budget: Vice Chancellor for research affair of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2017-10-02, 1396/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of duloxetine and pregabalin effects on plasma concentration of nitric oxide (NO) and inducible nitric oxide synthase (iNOS) in type 2 diabetic patients and the role of these mediators in neuropathic pain

Public title

Identification of the probable mechanisms of Duloxetine and Pregabalin involving in treatment of neuropathic pain of type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Type 2 diabetic patients with neuropathic pain which have the pain score over 4 on Visual Analogue Scale (VAS) for more than 3 months; 2- The age range: 40-60 years; 3- The patients should fill out and sign the consent forms
Exclusion criteria: 1- Hypersensitivity to Duloxetine and Pregabalin; 2-Kidney or liver failure; 3-Any other neuropathies (spinal cord injury, discopathy, congenital neuropathy, vocational, hypothyroidism, collagen vascular disease, vasculitis, Paraneoplastic disorders, immunological, alcoholism and drugs induced); 4- Rheumatoid Arthritis; 5-Goat; 6- Epilepsy; 7-Orthopedic complications; 8- Vision disability; 9-Intellectual disorders; 10-Usage of analgesic and anti-inflammatory drugs; 11-Type 1 diabetes; 12- Hypertension; 13-Smoking

AgeFrom **39 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****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**

School of Medicine Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

School of Medicine, Shahid Beheshti University of Medical Sciences, Koodakyar Avenue, Daneshjoo Blvd, Velenjak, Tehran

City

Tehran

Postal code

1985717443

Approval date

2016-04-26, 1395/02/07

Ethics committee reference number

IR.SBMU.MSP.REC.1395.41

Health conditions studied**1****Description of health condition studied**

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

2**Description of health condition studied**

Pain due to diabetic polyneuropathy

ICD-10 code

G63.2*

ICD-10 code description

Diabetic polyneuropathy

3**Description of health condition studied**

Autonomic neuropathy

ICD-10 code

G99.0

ICD-10 code description

Autonomic neuropathy in endocrine and metabolic diseases

Primary outcomes**1****Description**

Plasma concentration of Nitric Oxide Synthase

Timepoint

Before drug prescription and on days 30 and 60 after that

Method of measurement

ELISA kit

2

Description

Plasma concentration of Nitric oxide

Timepoint

Before drug prescription and on days 30 and 60 after that

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Pain

Timepoint

Before drugs prescription and every week after that

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Adverse drug reactions

Timepoint

Every day

Method of measurement

Interview with patients and their reports

Intervention groups

1

Description

Duloxetine group: Duloxetine 30 and 60 mg capsules, formulated by Sobhan pharmaceutical factory, Duloxetine 30 mg capsules will be prescribed once daily at first week, afterward, Duloxetine 60 mg capsules will be prescribed once daily for seven more weeks and before these eight weeks Duloxetine 30 mg placebo capsules (manufactured by Sobhan pharmaceutical factory) will be prescribed once daily for ten days

Category

Treatment - Drugs

2

Description

Pregabalin group: Pregabalin 75 and 150 mg capsules, formulated by Sobhan pharmaceutical factory, Pregabalin 75 mg capsules will be prescribed twice daily at first week, afterward, Pregabalin 150 mg capsules will be prescribed twice daily for seven more weeks and before these eight weeks Pregabalin 75 mg placebo capsules (manufactured by Sobhan pharmaceutical factory) will be prescribed twice daily for ten days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Dr. Anahita Fesharaki Nia

Street address

Diabetes Clinic, Mahdieh Hospital, Brujerdi Allay, Shishegar St., Fadaeian Eslam Avenue, Shuosh Square

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2

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Dr. Mir Saber Sadat Amini

Street address

Diabetes Special Clinic, Shohada Hospital, Tajrish Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The vice chancellor for research affairs of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Khojasteh Joharchi

Street address

Pharmacology Department, School of Medicine, Shahid Beheshti University of Medical Sciences, Koodakyar Avenue, Daneshjoo Blvd, Velenjak, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The vice chancellor for research affairs of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Sobhan Pharmaceutical Factory

Full name of responsible person

Dr. Khojasteh Joharchi

Street address

Pharmacology Department, School of Medicine,
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Koodakyar Avenue, Daneshjoo Blvd, Velenjak, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sobhan Pharmaceutical Factory

Proportion provided by this source

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

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Full name of responsible person

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Position

Pharm.D and Phd candidate student

Other areas of specialty/work

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Pharm.D and Phd candidate of Pharmacology

Other areas of specialty/work

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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