Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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
Age
From **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
City
Tehran

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
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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, 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

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

Name of organization / entity

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Moosareza Memari

Position

Pharm.D and Phd candidate student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Khojasteh Joharchi

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General Physician and Phd of Pharmacology

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Moosareza Memari

Position

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