

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effect of duloxetine on the mental state of patients with diabetic neuropathy (anxiety / depression)

Protocol summary

Study aim

Evaluation of efficacy and safety of duloxetine on mental status (anxiety / depression) of patients with diabetic neuropathy

Design

Clinical trial is performed on 30 patients by pre- and post-intervention method with one intervention group, non-corsaged, non-random, phase 2.

Settings and conduct

The study place is the office of supervisors and counselors (pain fellowship and endocrinologist), Specialist in the treatment of diabetic neuropathy and Evaluation of its effect and drug side effects on reducing depression and anxiety of patients for eligible patients (30 patients) prescribes duloxetine and He asks them to come back after 30 days of taking the medicine. The tool used to collect information is Beck Anxiety and Depression Inventory Which is completed by patients before and after the intervention. Also, side effects of the drug after the intervention and the amount of pain in patients are determined based on the VAS scale before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All diabetic patients aged 20 to 85 years with sensory diabetic neuropathy in the organs in which there are signs of anxiety or depression, referred to Dr. Rahmanian's office in 1401-1400. Exclusion criteria: non-cooperation of the patient in taking the drug, intolerance of the drug by the patient, pregnant women.

Intervention groups

We have only one intervention group That a specialist doctor to treat diabetic neuropathy and Investigating its effect on reducing depression and Anxiety of patients for them duloxetine in the form of 30 mg oral capsulesIt is prescribed twice a day (once every 12 hours) and should be consumed for up to 30 days.

Main outcome variables

Mental status (anxiety / depression) of patients based on

Beck questionnaire and drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210725051977N2**

Registration date: **2022-04-07, 1401/01/18**

Registration timing: **prospective**

Last update: **2022-04-07, 1401/01/18**

Update count: **0**

Registration date

2022-04-07, 1401/01/18

Registrant information

Name

Masoud Khoshbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 9893

Email address

masoudkhoshbin@iauyazd.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigation of the effect of duloxetine on the mental state of patients with diabetic neuropathy (anxiety / depression)

Public title
the effect of duloxetine on the anxiety and depression of patients with diabetic neuropathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 85 Diabetic patients with sensory diabetic neuropathy in organs with symptoms of anxiety or depression (ASA patients 1-3)
Exclusion criteria:
Lack of patient cooperation in proper drug use or response Drug intolerance by the patient Pregnant women

Age
From **20 years** old to **85 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ali Ibn Abi Talib Medical School (AS), Islamic Azad University, Yazd Branch

Street address

Safaieh, Alam Square, Boulevard of the Shohadaie Gomnam, Ali Ibn Abitaleb Medical School

City

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Province

Yazd

Postal code
8915813135

Approval date
2022-02-28, 1400/12/09

Ethics committee reference number
IR.IAU.YAZD.REC.1400.063

Health conditions studied

1

Description of health condition studied

Effect of Duloxetine on the Mental State of Patients (Anxiety) with Diabetic Neuropathy

ICD-10 code

E08.43

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy

2

Description of health condition studied

Effect of Duloxetine on the Mental State of Patients (Depression) with Diabetic Neuropathy

ICD-10 code

E08.43

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy

Primary outcomes

1

Description

Determination mental state (anxiety / depression) of patients with diabetic neuropathy based on Beck questionnaire

Timepoint

Determining the score of anxiety and depression at the beginning of the study (before the intervention) and 30 days after taking duloxetine

Method of measurement

Beck Anxiety and Depression Inventory questionnaire

Secondary outcomes

1

Description

Intensity of pain Fingers or toes based on VAS scale

Timepoint

Determining the score of anxiety and depression at the beginning of the study (before the intervention) and 30 days after taking Duloxetine

Method of measurement

Visual Analogue Scale

2

Description

Frequency of adverse drug complications (Duloxetine)
Timepoint
30 days after taking Duloxetine
Method of measurement
Check list including possible adverse drug reactions following Duloxetine

Intervention groups

1

Description

Intervention group: A group treated with duloxetine in the form of 30 mg oral capsules, Twice a day (every 12 hours) for 30 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal office of Dr Masoud Khoshbin - Pain fellow

Full name of responsible person

Dr Masoud Khoshbin

Street address

40th dead end, in front of Sepah, Shahid Sadoughi Boulevard, Yazd- Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Ahmad Shajari

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Masoud Khoshbin

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Masoud Khoshbin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Full name of responsible person

Nahid Ghorbani

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

En There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available