

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral Clonidine on the symptoms of peripheral neuropathy in diabetic patient. Randomized clinical trial.

Protocol summary

Study aim

Determining the effect of oral Clonidine on the symptoms of peripheral neuropathy in diabetic patients.

Design

In this clinical trial, 70 patients will be selected based on the inclusion criteria and will be randomly divided into experimental and control groups. Relevant questionnaires for each patient at the beginning of the study and 2, 4 and 8 weeks after the intervention. Will be filled in and then the information obtained will be evaluated. The study will use the Michigan Questionnaire, the McGill Pain Scale.

Settings and conduct

This study is performed among diabetic patients referred to Yasuj Diabetes Clinic who have neuropathy. Patients and the researcher of this study who has the task of examining patients unaware of how patients are treated and grouped. Patients are evaluated for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Patients with type 2 diabetes who have symptoms related to peripheral neuropathy. 2. No chronic diseases such as (cardiovascular disease, kidney disease and severe thyroid disorder), neurology or psychiatry 3. Are not pregnant or breastfeeding. 4. Do not take drugs that are effective in exacerbating or alleviating neuropathy 5. Age between 30 and 60 years old Exclusion criteria Having neuropathy for proven reasons other than diabetes Severe hypersensitivity to clonidine

Intervention groups

In this study, patients were divided into two experimental groups who, in addition to receiving the usual treatment for diabetic neuropathy, (took gabapentin) from clonidine at a dose of 0.2 mligram. The control group will also receive the usual treatment.

Main outcome variables

Severity of neuropathy, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211106052983N1**

Registration date: **2022-01-14, 1400/10/24**

Registration timing: **prospective**

Last update: **2022-01-14, 1400/10/24**

Update count: **0**

Registration date

2022-01-14, 1400/10/24

Registrant information

Name

soraya bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3323 3707

Email address

psychosein67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-16, 1400/10/26

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral Clonidine on the symptoms of peripheral neuropathy in diabetic patient. Randomized clinical trial.	
Public title	The effect of oral Clonidine on the treatment of diabetic neuropathy.
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients with type 2 diabetes who have symptoms associated with peripheral neuropathy. No chronic illness (cardiovascular, renal and thyroid disorders), severe neurology or psychiatry. Do not be pregnant or breastfeeding. Not taking medications that are effective in exacerbating or alleviating neuropathy. Age between 30 and 60 years old. Exclusion criteria: Having severe sensitivity to Clonidine Having neuropathy with proven reasons except Diabetes
Age	From 30 years old to 60 years old
Gender	Both
Phase	2-3
Groups that have been masked	- Investigator - Outcome assessor
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	They will be randomly divided into experimental and control groups. Randomization is by envelopes or Cards shuffling method. In this method, a number of cards selected by the researcher as the first group and the same number of cards for the next groups are considered; Then, by merging the cards with each other, a card is picked up and its allocation is recorded, and that card is returned to the total of the other cards. The cards are then merged again and another card is picked up. This process continues until a random sequence is reached according to the sample size. Also, the number of cards is not necessarily equal to the total number of samples. For example, in a three-group study with a sample size of 300 people and a ratio of 1: 1 groups, 3 cards can be prepared for each group.
Blinding (investigator's opinion)	Double blinded
Blinding description	The researcher performs clinical examination and registers information without knowing the group of patients
Placebo	Not used
Assignment	Factorial
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasouj University of Medical Sciences

Street address

No. 1, First floor dormitory complex, Saheli Street, in front of Imam Sajjad Hospital.

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591683677

Approval date

2021-04-08, 1400/01/19

Ethics committee reference number

.1400.008 .IR. YUMS. REC

Health conditions studied

1

Description of health condition studied

Diabet- Diabetic neuropathy.

ICD-10 code

E11.40

ICD-10 code description

Type 2 diabetes mellitus with diabetic neuropathy, unspecified.

Primary outcomes

1

Description

Severity of neuropathy in this study based on the Michigan Questionnaire, pain based on the McGill Pain Questionnaire.

Timepoint

Before the start of the study and 14, 28, 56 days later.

Method of measurement

The Michigan Questionnaire, the McGill Questionnaire, and the researcher-designed questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with diabetic neuropathy will

be treated with Gabapentin 100 mg every night and clonidine 0.2 mg every morning

Category

Treatment - Drugs

2

Description

Control group: Patients with diabetic neuropathy will be treated with gabapentin 100 mg capsule every night.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofateh Clinic - Diabetes Clinic

Full name of responsible person

Soraya Bagheri

Street address

Second floor, Diabetes Clinic, Mofteh Clinic, Army Boulevard.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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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

Yasouj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Yasouj University of Medical Sciences

Full name of responsible person

Soraya Bagheri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The spss data file includes groups, main variables and demographic variables

When the data will become available and for how long

After publishing the article extracted from the plan

To whom data/document is available

Those who have corresponded with the responsible author and have the necessary reason to receive the file

Under which criteria data/document could be used

We have not made a decision in this case and a decision will be made after reviewing the request

From where data/document is obtainable

Seyed Majid Ahmadi

What processes are involved for a request to access data/document

The applicant should send his request via email and after obtaining permission from all project partners, if the partners agree with his request, the data will be sent to him.

Comments