

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of enalapril on diabetic neuropathy; a double blind clinical trial

Protocol summary

Summary

The aim of this study was to investigate the effects of enalapril on diabetic neuropathy in patients 30 to 80-year-old with diabetes type 2. The sample size of this study is 124 people including 62 case and 62 control subjects. The main inclusion criteria of the study is having of type 2 diabetes and age between 30 to 80 years. All patients with underlying diseases or under previous treatment with enalapril will be excluded (main exclusion criteria). The duration of this study is 3 months that during this period the case group will be treated with enalapril (as the studying intervention) and the control group will receive multivitamin as placebo. Before and after the intervention the EMG-NCV study will be carried out on all patients in order to monitor the consequences of the study (including nerve conduction velocity, nerve conduction amplitude and nerve conduction latency).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061118063N1**

Registration date: **2014-11-09, 1393/08/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-09, 1393/08/18

Registrant information

Name

Ali Rajabpour Sanati

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Committee of Birjand University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of enalapril on diabetic neuropathy; a double blind clinical trial

Public title

Effect of enalapril on diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes type 2 diabetes based on the criteria of American Diabetes Association (blood sugar after 10 to 12 hours of fasting be more than 126 mg/dl or random BS equal or more than 200 mg/dl) at least for 3 years; Having mild to moderate neuropathy (grade 3 to 5 based on Michigan scoring system); Age between 30 to 80. Exclusion criteria: history of enalapril consumption during a recent year; Consumers of alcohol; Kidney disease patients; Liver disease patients (moderate to severe); The existence of a wound in the foot; amputation of the lower extremities; Developing gestational diabetes in women; history of hereditary neuropathy or background diseases causing neuropathy; Taking TCA antidepressants drugs; A lack of vitamin B12

(not less than 160mg/dl); A history of renal arteries stenosis; Having one kidney or micro-albuminuria; Sensitivity to ACD inhibitors; Long-term use of non-steroidal inflammatory drugs such as aspirin during the 4 weeks prior to the disease

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Birjand University of Medical Sciences

Street address

Moallem Blvd, Birjand, Iran

City

Birjand

Postal code

Approval date

2014-09-09, 1393/06/18

Ethics committee reference number

1393-06-01

Health conditions studied

1

Description of health condition studied

Diabetic Neuropathy

ICD-10 code

E10, E11

ICD-10 code description

Insulin-dependent diabetes mellitus, Non-Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

velocity of nerve conduction

Timepoint

before intervention - after intervention

Method of measurement

EMG-NCV

2

Description

amplitude of nerve conduction

Timepoint

before intervention - after intervention

Method of measurement

EMG-NCV

3

Description

latency (s) of nerve conduction

Timepoint

before intervention - after intervention

Method of measurement

EMG-NCV

4

Description

latency (m) of nerve conduction

Timepoint

before intervention - after intervention

Method of measurement

EMG-NCV

Secondary outcomes

empty

Intervention groups

1

Description

Case (intervention) group: after training on drug consumption and emphasis on contact the physician if confronted with drug side effects, they will treated with enalapril (Adibi pharmaceutical company) with 10 mg daily for 3 months. This study will be double-blinded, meaning that both the examiner and the patient will not be informed about the drug type.

Category

Treatment - Drugs

2

Description

Control group: treated with placebo (multivitamin from ShahrDarou pharmaceutical company), one tablet daily for three months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali-e-Asr Hospital

Full name of responsible person**Street address****City**

Birjand

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice-chancellor for research - Birjand University of
Medical Sciences**Full name of responsible person**

Dr. Zarban

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Moallem Blvd, Birjand, Iran

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Birjand

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceVice-chancellor for research - Birjand University of
Medical Sciences**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**

Birjand University of Medical Sciences

Full name of responsible person

Ali Rajabpour Sanati

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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