Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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

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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 enalpril (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
Street address
Moallem Blvd, Birjand, Iran
City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-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

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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