# 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 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
**Country**
Iran (Islamic Republic of)
**Phone**
+98 56 3234 1067
**Email address**
ali.poursanati@bums.ac.ir

**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

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Ali Rajabpour Sanati
**Position**
Medical Student
**Other areas of specialty/work**
**Street address**
Moallem Blvd, Birjand, Iran
**City**
Birjand
**Postal code**
**Phone**
+98 51 3234 1067
**Fax**
**Email**
ali.poursanati@bums.ac.ir; ali.poursanati@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Dr. Hamidreza Riasi
**Position**
Associate Professor
**Other areas of specialty/work**
**Street address**
Moallem Blvd, Birjand, Iran
**City**
Birjand
**Postal code**
**Phone**
+98 518825000
**Fax**
**Email**
riasi_h@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Ali Rajabpour Sanati
**Position**
Medical Student
**Other areas of specialty/work**
**Street address**
Moallem Blvd, Birjand, Iran
**City**
Birjand
**Postal code**
**Phone**
00
**Fax**
**Email**
ali.poursanati@bums.ac.ir; ali.poursanati@gmail.com
**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*