

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of vitamin B12 on the neuropathy of diabetic patients

Protocol summary

Study aim

Determining the effect of vitamin B12 on neuropathy in diabetic patients referred to Razi Birjand Hospital in 2024

Design

clinical trial with an intervention group, with a parallel group; Double blind, randomized

Settings and conduct

This study is conducted in Razi Birjand Hospital, South Khorasan Province. 80 patients with type 2 diabetes were randomly divided into two intervention or control groups (A-B). At the beginning and end of the study, the average score of pain, symptoms and severity of involvement of neuropathy is evaluated.

Participants/Inclusion and exclusion criteria

Our study population will be the number of 80 patients diagnosed with type 2 diabetes based on the criteria of the American Diabetes Association, referring to Razi Birjand Outpatient Neurology Clinic in 2024. Inclusion criteria: consent of patients to enter the study, suffering from diabetes for more than one year and exclusion criteria include: having an underlying disease such as myositis, connective tissue and joint disease, limb amputation, autoimmune disease, severe osteoarthritis, malignancy, fibromyalgia, failure kidney and liver, patients with ESRD, prolonged diabetes, vertebral discopathy, anemia, hypothyroidism and drug use.

Intervention groups

The intervention groups are as follows: Control group: receiving routine neuropathy drugs and intervention group: group receiving routine drugs + vitamin B12 1000 micrograms daily. The patients took the above medicines for 3 months and before and after the intervention (3 months after taking the medicine) the considered parameters are evaluated.

Main outcome variables

Average pain score, neuropathy symptoms and severity of neuropathy involvement based on muscle nerve strip

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N24**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

Registration date

2024-03-02, 1402/12/12

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin B12 on the neuropathy of diabetic patients

Public title

Evaluation of the effect of vitamin B12 on neuropathy in diabetic patients of Razi Hospital in Birjand in 2023

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction to enter the study Having diabetes for more than a year

Exclusion criteria:

Having an underlying disease such as myositis Having connective tissue and joint disease Limb amputation Having autoimmune disease Having severe osteoarthritis Malignancy Having fibromyalgia Having kidney and liver failure Patients with ESRD Prolonged diabetes Having vertebral discopathy Having anemia Having hypothyroidism Drug use

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

The placement of people in each group will be simple random and in a block method, in one of two control groups A: receiving routine neuropathy drugs and intervention group B: group receiving routine drugs + vitamin B12 divided daily 1000 micrograms will be One of these blocks will be randomly selected using the lottery method and the patients will be divided into one of two groups A or B. Then randomization is done for other patients as well. This will be done by the secretary.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome evaluator: The study leader (4th year neurology assistant) examines the symptoms of neuropathy at the beginning and end of the study without knowing the patients' placement in the drug group. The data analyst also does not know the placement of the patients and the type of drug they will receive, they will be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2023-11-27, 1402/09/06

Ethics committee reference number

IR.BUMS.REC.1402.343

Health conditions studied

1

Description of health condition studied

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

Pain

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Using the audio-visual pain scale questionnaire

2

Description

Symptoms and severity of neuropathy

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

By Using Nerve conduction velocity

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipients of routine neuropathy drugs, patients who have taken the above drugs for 3 months, and before and after the intervention (3 months after taking the drug), the relevant parameters are evaluated.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group: the group receiving routine drugs + vitamin B12 in the form of 1000 micrograms daily, the patients took the above drugs for 3 months, and before and after the intervention (3 months after taking the drug), the relevant parameters were evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Mesam Javadi

Street address

Neurology Clinic of Razi Hospital, Ghaffari Blvd, Iran- South Khorasan- Birjand,.

City

Birjand

Province

South Khorasan

Postal code

9717844471

Phone

+98 56 3136 6000

Email

razihospital@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Masoud Yosefi

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3238 1200

Email

research@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr Meysam Javadi

Position

Asistant Neurology

Latest degree

Ph.D.

Other areas of specialty/work

Neurology

Street address

School of Medicine, Birjand University of medical sciences, Ghahhari Blvd, Birjand, South Khorasan, Iran.

City

Birjand

Province

South Khorasan

Postal code

9717934888

Phone

+98 56 3238 1500

Email

oabstudent@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Hamidreza Riasee

Position

Member of the Faculty

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street address

Department of Neurology, School of Medicine, Birjand University of medical sciences, Ghahhari Blvd, Birjand Town

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3236 6000

Email

oabstudent@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaghegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Birjand University of medical sciences, Ghahhari Blvd, Birjand, South Khorasan, Iran.

City

Birjand

Province

South Khorasan

Postal code

9717934888

Phone

+98 915 104 6738

Email

zabihullahmohaghegh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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