

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effects of vitamin B12 supplementation in patients with diabetic peripheral neuropathy and low serum vitamin b12

#### Protocol summary

##### Study aim

The effects of vitamin B12 supplementation in diabetic peripheral neuropathy

##### Design

A total of 40 participants will be recruited and randomly assigned to 2 groups with a 1:1 allocation ratio. Random assignment will be done via block randomization.

##### Settings and conduct

Patients will be prescreened by telephone or face-to-face interview at 1 clinical of diabetes in Endocrinology and Metabolism Research Center (Tehran University of Medical Sciences, Tehran, Iran). All of investigators and patients involve will be masked to the treatments assignments until the study will be completed.

##### Participants/Inclusion and exclusion criteria

To be eligible for the study, patients will be satisfy the following criteria: male or female patients between 30 and 70 years of age, a MNSI 2 or higher, abnormal NCS, normal folate levels and low vitamin B12 levels. The main exclusion criteria from the study will be as follows: uncontrolled diabetes (HbA1c>9%), history of alcohol abuse, current smoker, current pregnancy or lactating women, diabetic foot , mental disease, heart failure, cancer, evidence of liver disease, impaired renal (GFR < 30)

##### Intervention groups

The patients will be received 1 capsule of 1000 mcg of vitamin B12 or 2 capsule of identical-looking two times daily for 4 months.

##### Main outcome variables

The primary endpoint was patient-reported neuropathy screening instrument (MNSI), and Neuropathy disability score (NDS) changes at 4 months.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210925052566N3**

Registration date: **2024-01-31, 1402/11/11**

Registration timing: **prospective**

Last update: **2024-01-31, 1402/11/11**

Update count: **0**

##### Registration date

2024-01-31, 1402/11/11

##### Registrant information

###### Name

Sayed Mahmoud Sajjadi Jazi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8822 0038

###### Email address

m\_sajadi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-29, 1402/12/10

##### Expected recruitment end date

2024-07-31, 1403/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of vitamin B12 supplementation in patients with diabetic peripheral neuropathy and low serum vitamin b12

##### Public title

vitamin B12 supplementation in patients with diabetic peripheral neuropathy

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Patients will eligible for recruitment with a MNSI of 2 or higher, abnormal NCS results age 30-70 years old low levels of vitamin B12

#### **Exclusion criteria:**

current pregnancy or lactating women, alcohol intake, current smoker, diabetic foot mental disease, heart failure, cancer evidence of liver disease (such as viral hepatitis, autoimmune hepatitis, etc.) impaired renal (GFR < 30) (HbA1c>9%)

### **Age**

From **30 years** old to **70 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

- Participant
- Outcome assessor

### **Sample size**

Target sample size: **40**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

50 patients with liver fibrosis, who have inclusion criteria and do not have exclusion criteria, based on a pre-designed random list (the list will be designed through the website

<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) will be randomly assigned to two groups to receive vitamin b12 (1000 mcg/d or 2000 mcg/d). Each drug package is assigned a code, the codes will be A and B. To reduce the bias in placing people in the treatment or placebo groups, patients will be randomly assigned to one of the two groups using the blocked randomization method (the size of the blocks is 2).

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

In this study, blinding will be done in the type of supplements for researchers and patients. In this way, the appearance of the capsules will be the same and their packaging will be the same. Coding (codes will be A and B) will be done by someone outside the study.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Research Ethics Committees of Endocrine & Metabolism Research Institute - Tehran University of Medic

##### **Street address**

Shariati Hospital, Kargar Shomali Ave.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1411713135

#### **Approval date**

2023-07-31, 1402/05/09

#### **Ethics committee reference number**

IR.TUMS.EMRI.REC.1402.041

## **Health conditions studied**

### 1

#### **Description of health condition studied**

diabetic peripheral neuropathy

#### **ICD-10 code**

E11.4

#### **ICD-10 code description**

Type 2 diabetes mellitus with neurological complications

## **Primary outcomes**

### 1

#### **Description**

Michigan neuropathy screening instrument (MNSI)

#### **Timepoint**

Baseline and 16 weeks

#### **Method of measurement**

Using standard scoring systems and questionnaires. Scoring is: Michigan neuropathy screening instrument , (0-10)

### 2

#### **Description**

Neuropathy disability score (NDS)

#### **Timepoint**

Baseline and 16 weeks

#### **Method of measurement**

Using standard scoring systems and questionnaires. Scoring is: Neuropathy disability score (0-10)

### 3

#### **Description**

Pain score

#### **Timepoint**

Baseline and 16 weeks

**Method of measurement**

Patients will be asked to score pain on a visual analog scale 0-10 with 10 being the worst pain ever

**4****Description**

Fasting glucose and HBA1c

**Timepoint**

Baseline and 16 weeks

**Method of measurement**

lab kit

**5****Description**

lipid profiles (HDL-c, LDL-c, TG, TC)

**Timepoint**

Baseline and 16 weeks

**Method of measurement**

lab kit

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: vitamin B12 500 mcg EuRovital (twice a day),The patients will be received 1 tablet of 500 mcg of vitamin B12 two times daily for 4 months.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: vitamin B12 1000 mcg EuRovital (twice a day),The patients will be received 2 tablet of 500 mcg of vitamin B12 two times daily for 4 months.

**Category**

Treatment - Drugs

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

clinical of diabetes in Endocrinology and Metabolism Research Center (Tehran University of Medical

**Full name of responsible person**

Asieh Mansour

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Shariati Hospital, Kargar Shomali Ave.

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**Phone**

+98 21 8822 0071

**Email**

asiehmansour@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Ali Akbari Sari

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Asieh Mansour

**Position**

asisstance professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Sayed Mamood Sajjadi -jazi  
**Position**  
associate professor  
**Latest degree**  
Subspecialist  
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Internal Medicine  
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## Person responsible for updating data

### Contact

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Asieh Mansour  
**Position**  
assistant professor  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Data collected for the primary and secondary outcomes will be shared.

### When the data will become available and for how long

Access starting 6 months after publication

### To whom data/document is available

The data will only be available for people working in academic institutions.

### Under which criteria data/document could be used

The data of the present study will only be accessible by for conducting Meta-analysis.

### From where data/document is obtainable

To access the required data, the researchers can contact Dr. Sayed Mahmoud Sajjadi Jazi: email address: mahmood.sajadi@gmail.com

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

The request will be assessed by the our group, and if all of us agree to the request, the requested data will be emailed.

### Comments