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
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Iran (Islamic Republic of)
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ali Akbari Sari
Street address
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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 updating data

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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