

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of effectiveness of methylcobalamin, alpha lipoic acid and vitamin B groups with placebo to control diabetic neuropathy syndrome in type 2 diabetes.

Protocol summary

Study aim

Primary Objective: To compare the efficacy of a daily dose of Dino versus a placebo on diabetic peripheral neuropathy (DPN) symptoms. Secondary Objectives: To evaluate the clinical safety of Dino in patients with diabetic peripheral neuropathy.

Design

To demonstrate the clinical efficacy, a clinical trial has been conducted involving 500 patients distributed across 8 centers in Iran, with 4 centers in Tehran and 4 centers in the provinces. The trial includes control and intervention groups, utilizing a parallel, double-blind, and randomized design. This study represents a post-market clinical trial conducted as a post marketing study. Stats Direct software was employed for randomization.

Settings and conduct

The patients with type 2 diabetes referring to 8 center will be selected for this study and randomly placed experimental or placebo group in the study centers, Tehran, Esfahan, Shiraz, Tabriz, Mashhad and Dino tablet and placebo will be given to patients randomly with the same similar packaging and investigators, patients are blinded, primary outcome is considered as scale of improvement of diabetic neuropathic symptom in these patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-80 years, diabetic neuropathy, neuropathic pain, numbness, tingling & burning sensation. Exclusion criteria: peripheral vascular disease, Pregnant or lactating women, Stroke, Alzheimer's Disease, Bell's Palsy, Parkinson's Disease, Epilepsy and Seizures, psychiatric and other neurological disorders

Intervention groups

Diabetic patients with peripheral neuropathy receiving the Dino tablet. Diabetic patients with peripheral neuropathy receiving placebo tablet.

Main outcome variables

tingling; Numbness; Pins and needles; Pain; vibration Sens

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221122056577N1**

Registration date: **2024-03-11, 1402/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-11, 1402/12/21**

Update count: **0**

Registration date

2024-03-11, 1402/12/21

Registrant information

Name

Mahsa Ghaffari

Name of organization / entity

Abba Daroo Teb

Country

Iran (Islamic Republic of)

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medco.mkt@naturesonly.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-11-23, 1403/09/03

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of effectiveness of methylcobalamin, alpha lipoic acid and vitamin B groups with placebo to control diabetic neuropathy syndrome in type 2 diabetes.

Public title
Effectiveness of methylcobalamin and alpha lipoic acid in diabetic neuropathy.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Male or female patients with diabetes mellitus type 2 and having peripheral neuropathy symptoms with ≥ 2 neuropathic pain scale scores. The age group must be between 18-80 years old. Symptomatic conditions with neuropathic pain, numbness, tingling & burning sensation in the extremities for at least 1 month before enrolling in the study. Consent and compliance with all aspects of the study protocol, methods, and providing data during follow up contact.
Exclusion criteria:
Presence of foot ulcer. Presence of peripheral vascular disease (non-palpable foot pulses, intermittent claudication). Patients who are contraindicated with Methylcobalamin, Alpha lipoic acid, folic acid, or vitamin B6 and B1 usage. Pregnant or lactating women. Patients with a history or presence of Stroke, Alzheimer's Disease, Bell's Palsy, Parkinson's Disease, Epilepsy and Seizures, psychiatric and other neurological disorders. Patients who are known cases of the kidney disorders. Hypothyroidism. Decompensated cirrhosis. Patients who consume alcohol or have a history of alcohol dependency followed by any current use. Current use or history of having received study investigational drugs or participated in any other clinical trial which ended in the preceding three months or is currently ongoing.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **500**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the multicenter nature of this study, a simple stratified randomization method (Based on centers),

using individual randomization within each stratum. To generate the random sequence, the RAND function in Excel software (Version 2302 Build 16.0.16130.20186) was utilized. The concealment of the randomization sequence took place in a location independent of the study site (drug production unit) without the knowledge of the research staff. Labels containing the code of each center and the corresponding patient number were created, and based on the mentioned random sequence and its matching with the designated product type in the sequence, they were affixed to the box containing the respective drug or placebo, ensuring that the research staff and patients remained unaware of the randomization sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

Aba Darou Teb company placed Dino supplement and placebo in the unique package and label and the code attached to each package with the same design and distributed between patients by non-notified person while patients and investigators are not informed about type of drugs. Also, health-care and staffs of clinic are not informed about type of drugs. Also, Outcome evaluator and analyzer are not informed about type of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences-school of medicine

Street address

Central Headquarters Building, Research and Technology Vice-Chancellor, Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway

City

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Province

Tehran

Postal code

1449614535

Approval date

2023-09-02, 1402/06/11

Ethics committee reference number

IR.IUMS.FMD.REC.1402.268

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

G99.0

ICD-10 code description

Autonomic neuropathy in endocrine and metabolic diseases

Primary outcomes

1

Description

Symptoms of diabetic neuropathy

Timepoint

Investigation of parameters would be performed throughout the treatment period followed by visit-I (baseline), visit-II (week 4), visit-III (week 8), and visit-IV (week 12).

Method of measurement

Vibration perception thresholds (VPT) through Biothesiometer, Visual Analog Scale (VAS), and Neuropathic Pain Scale (NPS) would be used to assess the patients on all four visits.

Secondary outcomes

1

Description

The safety of Dino

Timepoint

safety assessed during the course of study following Visit I (baseline), Visit II (week 4), Visit III (week 8), and Visit IV (week 12).

Method of measurement

For the analysis of secondary outcomes, all adverse drug reactions such as skin rash, nausea, gastrointestinal intolerance, or hypersensitivity to product components will be recorded through examination by the relevant study physician at all study visits, reviewed, and documented in the respective checklist(vital signs checklist) and reported by ADR questionnaire . Other vital signs will also be measured at each visit to detect potential hidden side effects and will be recorded and documented in the respective checklist(vital signs checklist). For instance, pulse rate will be measured using a digital pulse meter. Oxygen saturation will be measured using a pulse oximeter with the brand name Beurer and model type PO30. Similarly, respiratory rate will be manually counted by the researcher, and blood pressure will be measured using an Omron blood pressure monitor with model type M2 and as mentioned, it is recorded in the vital signs checklist.

2

Description

Examination of potential side effects, including skin rash

Timepoint

Adverse effects are evaluated during the course of study following Visit I (baseline), Visit II (week 4), Visit III (week 8), and Visit IV (week 12).

Method of measurement

For the analysis of secondary outcomes, all adverse drug reactions such as skin rash will be recorded through examination by the relevant study physician at all study visits, reviewed, and documented in the respective checklist(vital signs checklist) and reported by ADR questionnaire.

3

Description

Examination of potential side effects, including nausea.

Timepoint

Adverse effects are evaluated during the course of study following Visit I (baseline), Visit II (week 4), Visit III (week 8), and Visit IV (week 12).

Method of measurement

For the analysis of secondary outcomes, all adverse drug reactions such as nausea will be recorded through examination by the relevant study physician at all study visits, reviewed, and documented in the respective checklist(vital signs checklist) and reported by ADR questionnaire.

Intervention groups

1

Description

Intervention group: This group takes one Dino tablet daily for three months, which contains methyl cobalamin (1500 micrograms), alpha lipoic acid (100 mg), thiamine (10 mg), pyridoxine (3 mg) and folic acid (0.9 mg). Naturesonly company is the producer of Dino tablets.

Category

Treatment - Drugs

2

Description

Control group: Receiving placebo pill without having any active ingredient with the exact same appearance as the Dino pill, for three months and one a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikan Hospital

Full name of responsible person

Vahid Yousefi

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No. 6, Arag St., Artesh Blvd, Aghdasieh

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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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3

Recruitment center
Name of recruitment center
Dr. Nikousokhan Office
Full name of responsible person
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4

Recruitment center
Name of recruitment center
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Full name of responsible person
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5

Recruitment center
Name of recruitment center
Parsian Diabetes Clinic
Full name of responsible person
Aliakbar Raouf Saeb
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Lashgar Crossroads, Bahar St.
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6

Recruitment center
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7

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Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

8

Recruitment center

Name of recruitment center
Dr. Danafar office
Full name of responsible person
Faride Danafar
Street address
2nd Floor, Radiography Tabesh Building, Crossroad of Moaddel and Souratgar Ave.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Abba Darou Teb Co.

Proportion provided by this source

100

Public or private sector

Contact

Name of organization / entity
Abba Darou Teb Co.
Full name of responsible person
Mahsa Ghaffari
Position
Medico-Marketing Manager
Latest degree
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Person responsible for updating data

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Other areas of specialty/work

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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