Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

Phone
+98 21 8618 1631

Email address
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, Alphalipoic 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 deign 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

Tehran

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
Street address
No. 6, Arag St., Artesh Blvd, Aghdasieh
City
Tehran

Province
Tehran
Postal code
1937836814
Phone
+98 21 2912 0000
Email
yousefivahid15@gmail.com

2

Recruitment center
Name of recruitment center
Dr. Yousefi office
Full name of responsible person
Vahid Yousefi
Street address
1st floor, Physician Biulding 120, Rahmani Alley, Between 2nd and 3th Square, Tehranpars
City
Tehran
Province
Tehran
Postal code
1655815711
Phone
+98 21 4219 8592
Email
yousefivahid15@gmail.com

3

Recruitment center
Name of recruitment center
Dr. Nikousokhan Office
Full name of responsible person
Amir Kamran Nikousokhan
Street address
No.17, Shohada Alley, Uper of Motahari St., Mirzaye Shirazi St.
City
Tehran
Province
Tehran
Postal code
1586744744
Phone
+98 21 8872 8237
Email
amirkamranniko@yahoo.com

4

Recruitment center
Name of recruitment center
Dr. Samadani Fard Office
Full name of responsible person
Seyed Hossein Samadani Fard
Street address
No.5, First of Patris Lomomba St., After Bagherkhan, Sattarkhan St.
City
Tehran
Province
Tehran
Postal code
1443633133
Phone
+98 21 6691 5127
Email
samadanifard.h@iums.ac.ir

5

Recruitment center
Name of recruitment center
Parsian Diabetes Clinic
Full name of responsible person
Aliakbar Raouf Saeb
Street address
No.328, In Front of Subway Station, Bisim Crossroads, Lashgar Crossroads, Bahar St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137714315
Phone
+98 51 3858 4040
Email
dr.raoof@yahoo.com

6

Recruitment center
Name of recruitment center
Dr. Goharian Office
Full name of responsible person
Amir Reza Goharian
Street address
Ground Floor, Block T, Sakht Ajand Building, Amadgah St.
City
Isfahan
Province
Isfehan
Postal code
8145615957
Phone
+98 31 3224 0884
Email
amirreza.goharian@gmail.com

7

Recruitment center
Name of recruitment center
Dr. Shokrani Office
Full name of responsible person
Rahim Shokrani Houshmand
Street address
Emrouz Building, Taleghani Intersection, 17th Shahrivar St.
City
Tabriz

Province
East Azarbaijan
Postal code
5137718189
Phone
+98 41 3554 8135
Email
shokrani_dr@yahoo.com

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.
City
Shiraz
Province
Fars
Postal code
7134963479
Phone
+98 71 3231 3234
Email
danafar22@yhoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abba Darou Teb Co.
Full name of responsible person
Ali Mansouri Mehrabani
Street address
Golsa Tower, End of Afshar Alley, South Mofateh, Hafte Tir Squre.
City
Tehran
Province
Tehran
Postal code
1573758915
Phone
+98 21 8618 1631
Email
mansouri@naturesonly.ir
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
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Abba Darou Teb Co.
Full name of responsible person
Mahsa Ghaffari
Position
Medico-Marketing Manager
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Golsa Tower, End of Afshar Alley, South Mofateh, Hafte Tir Squre
City
Tehran
Province
Tehran
Postal code
1573758915
Phone
+98 21 8618 1631
Email
medco.mkt@naturesonly.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Haleh Chehrehgosha
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Education
Street address
Medica Faculty, Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1021
Email

chehrehgosha.h@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Haleh Chehrehgosha

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Medical Education

Street address
Medical Faculty, Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 1021

Email
chehrehgosha.h@iums.ac.ir

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