Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Investigating the effect of alpha lipoic acid on neuropathy in patients with type 2 diabetes.

Protocol summary

Study aim
Determining the effect of alpha lipoic acid on the symptoms of neuropathy in patients with type 2 diabetes

Design
The study groups are made up of eligible people who visit the diabetes clinic of the hospital. These patients are studied consecutively and under the condition of Ard's consent. Patients are assigned to one of two intervention or control groups using random block design. The sample size is expected to be 80 people. The study phase is 3.

Settings and conduct
After entering to the study and getting consent, and with a clinical history of neuropathy, in addition to their routine medications, patients receive alpha lipoic acid capsules. Patients are entered sequentially and sampling will continue until the research samples are completed. The control group will also receive a similar placebo. The patients of both the intervention and control groups will be referred to the clinic of Ziyaian Hospital of Tehran University of Medical Sciences. The patients and the prescribing doctor will not know which person has been assigned to the intervention group and which one to the control group, because drugs and placebo are designed exactly the same. Blinding is in the sense that the view and understanding of the patient as well as the doctor is not affected by the type of medicine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 74 years Having type 2 diabetes The presence of peripheral neuropathy (pain) in the examination Exclusion criteria: Non-entry criteria Presence of neurological disease such as MS Severe liver or kidney disease, etc

Intervention groups
The intervention group received 300 mg alpha lipoic acid capsules twice a day The control group receives a placebo capsule of 300 mg with the same shape and design at the same time

Main outcome variables
Neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230303057599N2**
Registration date: **2023-07-13, 1402/04/22**
Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**
Update count: **0**

Registration date
2023-07-13, 1402/04/22

Registrant information

Name
Mahdi Shafiee Sabet

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7707 8738

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-01, 1402/05/10

Expected recruitment end date
2024-02-29, 1402/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of alpha lipoic acid on neuropathy in patients with type 2 diabetes.

Public title
The effect of alpha lipoic acid on neuropathy in patients with type 2 diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 74 years, Type 2 diabetes, duration of diabetes more than one year, presence of peripheral neuropathy (pain) in the examination, symptoms of neuropathy (pain) for at least one month, score more than three in the pain diagnostic questionnaire.

Exclusion criteria:
neurological disease such as MS Severe liver or kidney disease Antioxidant consumption in the last three months The presence of cancer and malignancy and chemotherapy Pregnancy and breastfeeding Peripheral arterial disease diabetic foot ulcer

Age
From **18 years** old to **74 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocks of 4 and 6 will be used for randomization in order to assign patients individually and with equal numbers to intervention and control groups. Random allocation software can also be used. patient's allocation group after consultation and consent. Opaque sealed envelopes will be used to conceal allocations.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the research samples are not aware of which drug or placebo they are receiving. Also, the prescribing doctor is not aware of the drug. Only the principal investigator will know whether A or B is drug or placebo. Also, the data analyst will not know which data are for the intervention group and which are for the control group. Medicines are ordered in the form of capsules with the same color, shape and weight for both groups, and it will not be possible for the patient and the prescribing doctor to distinguish them.

Placebo
Used

Assignment
Parallel

Other design features
Patients are consecutively entered into the study and if there are entry criteria and consent to entry, they are allocated to each of the intervention or control groups by random block. The intervention group receives capsules of 300 mg of alpha lipoic acid and the control group receives capsules with the same shape and design, without medicinal substances.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Medicine - Tehran University of Medical Sciences (Research Ethics Committee)

Street address
Poorsina

City
Tehran

Province
Tehran

Postal code
88953003

Approval date
2021-08-14, 1400/05/23

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.538

Health conditions studied

1

Description of health condition studied
Diabetes - type 2

ICD-10 code
E08.40

ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Neuropathy

Timepoint
At the beginning of the study and then once a month until the completion of the probationary period

Method of measurement
Physical examination

2

Description

pain

Timepoint

At the beginning of the study and then once a month until the completion of the probationary period

Method of measurement

visual analog scale for pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive 300 mg capsules of alphalipoic acid (Raha Pharmaceutical Company) twice a day. In order to receive the capsule, the necessary educational explanations are given by the doctor to both the intervention and control groups. Also, all the drugs used by the patients in both groups will be recorded. In addition, these patients have routine tests of CBC, blood sugar, etc. The patients will be given medicine for one month and at the end of the first, second and third month they will be examined. Also, information is obtained from the patients' compliance with alphalipoic acid medication. Patients only know that they are under research and have consented to enter the study, but they are not aware of receiving drugs or placebo.

Category

Treatment - Drugs

2

Description

Control group: After obtaining consent following the review of entry criteria, the patients assigned to the control group will receive a placebo(Raha Pharmaceutical Company) instead of alphalipoic acid capsules, which the patients and the prescribing doctor do not know whether it is a drug or a placebo. The patients will receive the medicine for one month and will return every month, and the intervention group will receive all the training and examinations from the prescribing doctor. Also, the patient will be asked about the consumption of capsules. Medications taken by the patient are also checked and recorded during the course

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaeian Hospital

Full name of responsible person

Mahdi Shafiee Sabet

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Qala Morghi St. - Abu Dhar St., District 17 Municipality

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Mahdi Shafiee Sabet

Position

Faculty member

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

Mahdi Shafiee Sabet

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

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

Data Dictionary

Not applicable

Title and more details about the data/document

To share the data, all the data after deidentification in the form of excel or spss files regarding all the desired consequences can be provided to the officials of the ministry to help in developing the protocol. Also, researchers can get the file after the request from the link that will be designed.

When the data will become available and for how long

Access starts three months after the publication of the article

To whom data/document is available

Hospital managers and doctors with permission from the principal investigator

Under which criteria data/document could be used

For the purpose of secondary analysis on the data by presenting the approved design code

From where data/document is obtainable

Dr. Mahdi Shafiee Sabet mshafiees@sina.tums.ac.ir

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

The request can be made in writing and officially by the registration in the automation system, etc. to the main researcher

Comments