Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of synbiotic on quality of life, sleep interference, pain, and metabolic indices of patients with painful diabetic neuropathy

Protocol summary

Study aim

Assessment of the effect of synbiotic on pain, quality of life, sleep disorder, and metabolic indices of patients with painful diabetic neuropathy

Design

A randomized, triple-blind, parallel trial with one intervention and one control group

Settings and conduct

Participants selection for this study begins after approval at the Research Vice-Chancellor and the Ethics Committee of the Faculty of Health and Nutrition Sciences, University of Iran. The participants of this study are selected from the patients referred to the Endocrine and Metabolism Research Institute of Iran University of Medical Sciences who are willing to cooperate with the project.

Participants/Inclusion and exclusion criteria

Diagnosing diabetes and peripheral diabetic neuropathy based on the patient's record according to the doctor's diagnosis Patients aged 35 to 70 years No pregnancy or breastfeeding Stable blood sugar control with an HbA1C level of less than 8% based on the patient's record stably receiving antidiabetic drugs without changing their type and dosage for 30 days before randomization NRS score of at least 4 out of ten averaged over 24 hours per day for at least one week before the start of the study No other chronic diseases such as kidney and liver failure, cancer, etc. Not taking supplements or receiving a special diet in the three months before the start of the study Willingness, contentment, and ability to carry out and complete the study and cooperate with the researcher

Intervention groups

Intervention group: 30 people based on inclusion criteria will receive one synbiotic capsule (containing probiotic and prebiotic) daily for 8 weeks. Control group: 30 people will receive identical capsules as the intervention group but without synbiotics daily for 8 weeks.

Main outcome variables

Pain level, quality of life, sleep interference, anthropometric indicators, fasting blood sugar, insulin, HOMA-IR.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090901002394N49**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

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Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-28, 1402/05/06

Expected recruitment end date

2024-07-27, 1403/05/06

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of synbiotic on quality of life, sleep interference, pain, and metabolic indices of patients with painful diabetic neuropathy

Public title
The effect of synbiotic in painful diabetic neuropathy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosing diabetes based on the patient's record according to the doctor's diagnosis based on the criteria of the American Diabetes Association for at least one year before the start of the study. Diagnosing peripheral diabetic neuropathy based on the patient's record according to the doctor's diagnosis based on the criteria of the American Diabetes Association for at least three months before the start of the study (based on the results of small fiber function, including the feeling of temperature or pinprick, as well as the results of large-fiber function including vibration feeling using 128 Hz tuning fork and 10-g monofilament) Patients aged 35 to 70 years No pregnancy or breastfeeding Stable blood sugar control with an HbA1C level of less than 8% based on the patient's record stably receiving antidiabetic drugs without changing their type and dosage for 30 days before randomization NRS score of at least 4 out of ten averaged over 24 hours per day for at least one week before the start of the study No other chronic diseases such as kidney and liver failure, cancer, etc. Not taking supplements or receiving a special diet in the three months before the start of the study Willingness, contentment, and ability to carry out and complete the study and cooperate with the researcher
Exclusion criteria:
People with immunodeficiency, short bowel syndrome (SBS), inflammatory bowel disease People with central venous catheters or heart valve disease People with hypothyroidism and other thyroid disorders People with non-diabetic neuropathies, including drug-induced neuropathy (such as isoniazid and chemotherapy), paraneoplastic neuropathy, spinal cord diseases such as intervertebral disc herniation People with pregnancy or expect to be pregnant during the study, as well as Breastfeeding Mother People receiving drugs or supplements or antibiotics not determined in the research People who, according to the researcher, have psychological, medical, and medicinal characteristics that put their mental and physical health at risk during the study (such as people with severe anxiety, severe depression, mania, dementia, history of drug and alcohol addiction) Inadequate education and/or ability to interview
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the samples, first, a list of 60 items is generated by computer random number generation using random allocation software version 1.0.0 that is publicly available, into two groups of 30 items labeled as A or B. This list is provided to the researcher. eligible participants are allocated to either group A or B. The manufacturer of the placebo is asked to put one of the labels A or B on the synbiotics and the other on the placebo by throwing a coin and keeping this confidential until the end of the data analysis. Therefore the synbiotics are indicated with one of the letters A or B, and the placebos by the other letter. According to the randomization table, the researcher will distribute the synbiotic and placebo according to the order of reference of the samples from packages A or B.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This research is a triple-blind clinical trial study in which participants, researchers, and data analysts will not know the type of intervention (placebo and synbiotic) received by the participants during the study. blinding of the participants will be done by using indistinguishable synbiotic and placebo. participants in the placebo group will be provided with placeboes identical to those in synbiotic group that are identical in terms of color, scent, and taste but filled with Lactose monohydrate, talc, magnesium stearate, maltodextrin, Avicel, sodium starch, and aerosol. in order to blind the researcher and data analyst, The manufacturer of the placebo is asked to put one of the labels A or B on the drug and the other on the placebo by throwing a coin and keep this confidential until the end of the data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Iran University of Medical Sciences
Street address
Iran University of Medical Sciences-near Milad Hospital-between the intersection of Sheikh Fazlollah Nouri and Shahid Chamran-Shahid Hemmat Highway
City
tehran
Province
Tehran
Postal code
1449614535
Approval date
2023-05-23, 1402/03/02
Ethics committee reference number
IR.IUMS.REC.1402.126

Health conditions studied

1

Description of health condition studied
Painful diabetic neuropathy
ICD-10 code
G63
ICD-10 code description
Polyneuropathy in diseases classified elsewhere

Primary outcomes

1

Description
fasting blood sugar
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
laboratory test

2

Description
INSULIN
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
laboratory test

3

Description
HOMA-IR
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
calculation

4

Description
Type and intensity of pain
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
short form McGill pain questionnaire-2 (SF-MPQ2)

5

Description
pain intensity
Timepoint
Before intervention and at the end of each week until the end of the Eighth week
Method of measurement
numeric rating scale questionnaire

6

Description
Insomnia Severity
Timepoint
8 weeks
Method of measurement
Insomnia Severity index questionnaire

7

Description
Sleep Interference Scale
Timepoint
Before intervention and at the end of each week until the end of the Eighth week
Method of measurement
Sleep Interference Scale questionnaire

8

Description
quality of life
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
SF-36 quality of life questionnaire

Secondary outcomes

1

Description
Weight
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
scale

2

Description
Body mass index
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
calculation

3

Description
Waist circumference
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
متر نواری

4

Description
systolic blood pressure
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
blood pressure monitor

5

Description
Diastolic blood pressure
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
blood pressure monitor

Intervention groups

1

Description
Intervention group: 30 patients with painful diabetic neuropathy receiving FamiLact synbiotic containing 10 to 9 CFU of Lactobacillus rhamnosus, Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus plantarum, Bifidobacterium breve, Bifidobacterium longum, Bifidobacterium bifidum, Bifidobacterium lactis, Streptococcus thermophilus species as probiotics. and Fructooligosaccharides (FOS) as prebiotics, manufactured by ZIST TAKHMIR Company for 8 weeks.
Category
Treatment - Other

2

Description
Control group: 30 participants in the placebo group (capsules completely similar to the synbiotic group in terms of color, smell, and taste, but filled with lactose monohydrate, talc, magnesium stearate, maltodextrin, Avicel, sodium starch, and aerosol), manufactured by the ZIST TAKHMIR company for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Institute of endocrinology and metabolism
Full name of responsible person
mohammad ebrahim khamseh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page 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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Manoochehr Amin Amlashi
Position
Master student in nutrition sciences
Latest degree
Bachelor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about primary and secondary outcomes will be available upon request from the researcher.
When the data will become available and for how long
The data will be available 6 months after the results are published.
To whom data/document is available
The data will be available to all researchers.
Under which criteria data/document could be used
The data will be available for research purposes only.
From where data/document is obtainable
Manoochehr Amin Amlashi: Email: ManoochehrAminAmlashi@gmail.com Shima Jazayeri: Email: sh_jazayeri@tums.ac.ir
What processes are involved for a request to access data/document
The request should be made via email to the researchers. The data will be available after the request is reviewed.
Comments