Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of curcumin and bromelain on anxiety, stress, depression, quality of life and sleep quality in diabetic neuropathy patients.

Protocol summary

Study aim
Determining the effect of curcumin and bromelain on anxiety, stress, depression, quality of life and sleep quality in patients with diabetic neuropathy.

Design
Clinical trial of control group drug, with parallel groups, triple blind, randomized, phase 3 on 100 patients

Settings and conduct
After receiving the code of ethics and the code of IRCT.The eligible patients will be randomly assigned to the supplement group (combination of curcumin and bromelain) and placebo (lactose). Questionnaires will be completed at the beginning and end of the study and the participants will not stop receiving the standard treatment. Daily intervention group 2 They will receive capsules containing curcumin and bromelain for 8 weeks. The control group will consume the same amount of placebo or lactose. The patient is the therapist and the analyst.

Participants/Inclusion and exclusion criteria
People with diabetic neuropathy in the age range of 40 to 65 years with a BMI in the range of 18.5 to 30 are included in the study. Patients with pineapple allergy, patients with neurological diseases that cause neuropathy, patients who are taking drugs that interfere with treatment such as Nerve drugs such as SSRIs, antidepressants and anti-stress drugs, and non-steroidal anti-inflammatory drugs, or patients who take anticoagulant drugs, patients who have foot ulcers, visual disturbances, and dizziness are not included in the study.

Intervention groups
The intervention group will receive 2 capsules containing curcumin and bromelain daily, with a dose of 150 mg of bromelain equivalent to 375 GDU and 300 mg of curcumin per capsule for 8 weeks. The control group will consume the same amount of placebo or lactose.

Main outcome variables
Anxiety, stress, depression, quality of life and quality of sleep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191105045340N5**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date
2024-06-22, 1403/04/02

Registrant information

Name
Seyedeh Tayebeh Rahideh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8670 4843

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of curcumin and bromelain on anxiety, stress, depression, quality of life and sleep quality in diabetic neuropathy patients.

Public title
The effect of curcumin and bromelain in patients with diabetic neuropathy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having type 2 diabetes based on the diagnosis of a specialist doctor Diabetic neuropathy in this study will be based on the diagnosis of a specialist doctor and clinical or paraclinical diagnostic criteria. Willingness to cooperate Age 40 to 65 years BMI of people should be in the range of 18.5 to 30 Absence of leg ulcers, visual disturbances and dizziness

Exclusion criteria:
Allergy to pineapple Having neurological diseases that cause neuropathy. Taking drugs that interfere with treatment, such as neuroleptics such as SSRIs, antidepressants and anti-stress drugs, and non-steroidal anti-inflammatory drugs Taking anticoagulants

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with the inclusion criteria will be assigned to groups A or B based on a randomized list generated by using the technique of quadruple blocks procured from a software application known as Random Number Calculator. For the production of placebo, coordination will be made with Salamat Parmon Amin manufacturing company. It is requested that the drug manufacturer label the drug or placebo with a letter A or B, determined by a coin toss, and the opposite letter shall be assigned to the alternative option.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This interventional study will be conducted in a triple blind manner. Blinding includes patient, therapist and analyst. In order to make a placebo, coordination will be done with Salamat Parmon Amin production company and it is requested that the drug manufacturer put one of the letters A or B on the drug or placebo and the other letter on the other by using a lottery by throwing a coin. The confidentiality of both the drug and placebo types should be maintained until the conclusion of the data analysis, as a fundamental element of the research protocol, and after the analysis, the researcher will ask the person in charge of the drug manufacturing for the type of labels. This means that the therapist will not know the type of medicine or whether the medicine packages are placebo. Neither the patient nor the analyst will know about this. The placebo capsules will bear complete resemblance to the capsules of the intervention group in terms of their coating, color, and smell.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2024-05-11, 1403/02/22

Ethics committee reference number
IR.IUMS.REC.1403.099

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy

ICD-10 code
E08.40

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

Primary outcomes

1

Description

Depression

Timepoint

Before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

Questionnaire DASS-21

Secondary outcomes

1

Description

Anxiety

Timepoint

Before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

Questionnaire DASS-21

2

Description

Stress

Timepoint

Before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

Questionnaire DASS-21

3

Description

Quality of life

Timepoint

Before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

SF-36 questionnaire

4

Description

Sleep quality

Timepoint

Before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

Petersburg Questionnaire (PSQI)

Intervention groups

1

Description

Intervention group: The intervention group consumes 2 capsules of the combined supplement of curcumin and bromelain each day, each capsule containing 150 mg of bromelain equivalent to 375 GDU and 300 mg of curcumin for 8 weeks.

Category

Treatment - Other

2

Description

Control group: The control group consumes 2 placebo capsules daily for 8 weeks. The placebo capsule contains lactose.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Dr.Seyedeh Tayebeh Rahideh

Street address

Corner of Mansouri St, Niayesh St., Sattar Khan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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
Dr.Seyedeh Tayebeh Rahideh

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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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