Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the effect of quercetin and bromelain co-supplementation (capsule of Brozyme Plus) on some inflammatory indices, oxidative stress, and clinical signs in patients with Parkinson's disease: A triple-blind randomized controlled clinical trial

Protocol summary

Study aim

To determine and compare the effects of co-supplementation of quercetin and bromelain on selected inflammatory and oxidative stress biomarkers, as well as clinical symptoms, in individuals with Parkinson’s disease before and after the intervention.

Design

A controlled, randomized, triple-blind clinical trial with parallel groups, phase 3 on 90 patients with Parkinson's disease.

Settings and conduct

This clinical trial will be conducted in patients with Parkinson’s disease at the neurologist's clinic in Isfahan city. Participants will receive either capsules of Brozyme Plus or placebo in identical packages for 12 weeks.Participants, investigators responsible for interviews and sampling, laboratory assessors, and statisticians will remain blinded to group allocation throughout the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 45 years old or more; Diagnosis of Parkinson's disease based on United Kingdom PD Society Brain Bank (UKPDSBB)criteria; Having the Hoehn and Yahr score less than 5; BMI equal or less than 40; Non-inclusion criteria: Adherence to a specific diet or consumption of quercetin and bromelain supplement in the last 3 months; Take of immunosuppressive medications, or use of medications that may interact with quercetin and bromelain supplements, such as warfarin, Patients with other neurodegenerative diseases such as Huntington's disease, multiple sclerosis (MS), Wilson's disease; Central nervous system infections such as meningitis; having a Hoehn and Yahr score of 5 out of 5; History of allergy to quercetin and bromelain.

Intervention groups

Intervention: 800 mg of quercetin and 165 mg bromelain per day, for 12 weeks. Control group: 965 mg of magnesium stearate, for 12 weeks.

Main outcome variables

Indices of inflammation and oxidative stress, disease stage, sleep quality, cognitive status, quality of life, mental health, and appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N13**
Registration date: **2026-05-30, 1405/03/09**
Registration timing: **prospective**

Last update: **2026-05-30, 1405/03/09**
Update count: **0**

Registration date

2026-05-30, 1405/03/09

Registrant information

Name
Mohammad bagherniya
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-12-31, 1405/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of quercetin and bromelain co-supplementation (capsule of Brozyme Plus) on some inflammatory indices, oxidative stress, and clinical signs in patients with Parkinson's disease: A triple-blind randomized controlled clinical trial

Public title

The effect of quercetin and bromelain co-supplementation (capsule of Brozyme Plus) on Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Provision of informed consent and willingness to participate in the study Men and women (postmenopausal women) aged 45 years or older Parkinson’s disease diagnosed according to the UK Parkinson’s Disease Society Brain Bank diagnostic criteria (UKPDSBB). Hoehn and Yahr stage <5 Body Mass Index (BMI) ≤40 kg/m²

Exclusion criteria:

Adherence to a specific diet or consumption of quercetin or bromelain supplements within the past three months. Take of immunosuppressive medications, or use of medications that may interact with quercetin and bromelain supplements, such as warfarin. Diagnosis or history of other neurodegenerative disorders, including Huntington’s disease, multiple sclerosis (MS); Wilson’s disease, central nervous system infections, such as meningitis. Hoehn and Yahr stage of 5 out of 5. History of allergy to quercetin or hypersensitivity to grapes . History of allergy to bromelain or hypersensitivity to pineapple, celery, fennel, or carrot.

Age

From **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the intervention and placebo groups using a stratified block randomization method with a block size of 4 and individual as the unit of randomization. For this purpose, people will be classified into 4 states based on the variables of gender and stage of the disease and people with the same states will be randomly assigned to intervention and placebo groups in a 1:1 ratio.The random sequence will be generated using a software-based random number generator provided by www.sealedenvelope.com/simple, and the allocation process will be performed by an independent researcher. In addition, allocation concealment will be ensured using opaque, sealed, and sequentially numbered envelopes containing group codes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be designed as a triple-blind randomized clinical trial. Capsules of Brozyme Plus (containing Quercetin and bromelain) and placebo will be prepared to be identical in color, shape, odor, and route of administration, and will be provided in identical packaging so that participants cannot distinguish between them, ensuring participant-level blinding. For blinding, the products will be labeled with coded identifiers A and B, and the true identity of each code will be known only to an independent researcher not involved in the trial. Participants, investigators responsible for interviews and sampling, laboratory assessors, and statisticians will remain blinded to group allocation throughout the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

City

Esfahan

Province

Isfehan

Postal code

8174673461

Approval date

2026-04-17, 1405/01/28

Ethics committee reference number

IR.MUI.MED.REC.1405.018

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Tumor necrosis alpha factor(TNFα)

Timepoint

Before and after intervention

Method of measurement

ELISA test

2

Description

Malondialdehyde (MDA)

Timepoint

Before and after intervention

Method of measurement

Commercial Malondialdehyde Kit by Colorimetric Method

3

Description

C reactive Protein (CRP)

Timepoint

Before and after intervention

Method of measurement

ELISA test

4

Description

stage of disease

Timepoint

Before and after intervention

Method of measurement

Hoehn and Yahr scale

5

Description

Interleukin 6

Timepoint

Before and after intervention

Method of measurement

ELISA Test

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and after intervention

Method of measurement

Parkinson's Disease Questionnaire - 39 (PDQ-39)

2

Description

Mental Health (Depression, Anxiety , Stress)

Timepoint

Before and after intervention

Method of measurement

Depression Anxiety Stress Scale -21 (DASS)

3

Description

Sleep Quality

Timepoint

Before and after intervention

Method of measurement

Parkinson's Disease Sleep Scale (PDSS)

4

Description

Appetite

Timepoint

Before and after intervention

Method of measurement

Simplified Nutritional Appetite Questionnaire (SNAQ)

5

Description

Cognitive Status

Timepoint

Before and after intervention

Method of measurement

Abbreviated Mental Test (AMT)

6

Description

Anthropometric Index

Timepoint

Before and after intervention

Method of measurement

Scale and Stadiometer

7

Description

Blood pressure

Timepoint

Before and after intervention

Method of measurement

Digital Blood Pressure Monitor

8

Description
SOD
Timepoint
Before and after intervention
Method of measurement
Commercial superoxide dismutase diagnostic kit using the colorimetric method

9

Description
Total Antioxidant Capacity(TAC)
Timepoint
Before and after intervention
Method of measurement
Commercial Total Antioxidant Capacity kit using the colorimetric method

10

Description
Interleukin 1 beta
Timepoint
Before and after intervention
Method of measurement
ELISA Test

Intervention groups

1

Description
Intervention: Two capsules of Brozyme Plus per day from the Office of Tachra pharmed, each containing 400 mg quercetin and 82.5 mg bromelain, (total daily dose: 800 mg quercetin and 165 mg bromelain), for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Two placebo capsules per day from the Office of Tachra pharmed, each containing 482.5 mg of magnesium stearate (total daily dose: 965 mg), for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinic of Al-Zahra Hospital
Full name of responsible person
Sadaf Esfahanizade
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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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Research and Technology Deputy, Isfahan University of Medical Sciences, Hazar Jarib Street
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position

Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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