Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the Effect of Ginger Supplementation on Antioxidant and oxidant Markers, Clinical Outcome and Quality of Life in Patients with Parkinson's Disease: Double-blind, parallel, randomized controlled trial

Protocol summary

Study aim

This study aims to compare demographic, clinical and nutritional characteristics of patients with Parkinson's disease and to evaluate the effects of ginger supplementation on Antioxidant and oxidant Markers, Clinical Outcome, quality of life and body mass index compared with placebo.

Design

This is a randomized, double blind, parallel, placebo controlled clinical trial using stratified balanced block randomization.

Settings and conduct

A total of 48 patients will be recruited from the Isfahan Parkinson Charity Association. After a two week run in period, the intervention group will receive 1000 milligrams of ginger powder daily and the control group will receive placebo for 12 weeks.

Participants/Inclusion and exclusion criteria

Patients aged 50 to 80 years with Parkinson's disease, body mass index above 18.5 and stable medication will be included. Exclusion criteria include special diets, recent ginger or antioxidant supplement intake, thyroid disorders, severe psychiatric or cognitive disorders, smoking, alcohol use, anticoagulant, anti inflammatory, immunosuppressive drugs or insulin use.

Intervention groups

Participants will be randomly allocated to ginger or placebo groups.

Main outcome variables

Serum levels of Superoxide dismutase, Glutathione peroxidase, total antioxidant capacity, total oxidant status, Parkinson's disease severity using the Movement Disorder Society Unified Parkinson's Disease Rating Scale and Hoehn and Yahr scale, quality of life, body mass index, energy and nutrient intake and physical activity will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251028067794N1**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date

2026-04-22, 1405/02/02

Registrant information

Name

Maziar Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-07-22, 1405/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Ginger Supplementation on Antioxidant and oxidant Markers, Clinical Outcome and Quality of Life in Patients with Parkinson's Disease: Double-blind, parallel, randomized controlled trial

Public title

Investigating of the Effect of Ginger Supplementation in Patients with Parkinson’s Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 50 and 80 years Body Mass Index (BMI) greater than 18.5 Patients willing to participate in the study and able to provide written informed consent Diagnosis of Parkinson’s disease confirmed by a neurologist based on established diagnostic criteria Stable medication regimen for at least one month prior to the beginning of the study

Exclusion criteria:

Following specific dietary regimens (such as ketogenic, fasting, etc.) within one month before the start of the study Consumption of ginger-enriched products within one month before the start of the study Presence of hypo- or hyperthyroidism Presence of severe psychosis or other concurrent neurological disorders Cognitive impairment based on the MOCA criteria Mood disorders such as severe depression, bipolar disorder, or severe anxiety (as determined by a neurologist) Known allergy or hypersensitivity to ginger Hoehn and Yahr score equal to 5 Use of cigarettes, nicotine, or alcohol Use of anticoagulant medications Use of anti-inflammatory or immunosuppressive drugs Receiving insulin therapy Use of antioxidant supplements

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using stratified block randomization with balanced blocks of size 4 and an allocation ratio of 1:1. The randomization process will be stratified based on sex and disease severity according to the Hoehn and Yahr scale. The random allocation sequence will be generated by the study statistician using the Sealed Envelope online randomization system. The sequence will then be stored in a password-protected file inaccessible to the research team. Only the clinical officer of the Parkinson Charity Association, who is not involved in assessments or data collection, will have access to the sequence. Based on this sequence, ginger supplement bottles and placebo bottles will be prepared to be visually identical and labeled with sequential numeric codes. The bottles will be placed inside opaque, sealed, and tamper-proof envelopes. Each participant will receive the envelope corresponding to their assigned code only after confirming eligibility and completing baseline assessments. Researchers, healthcare providers, outcome assessors, and participants will remain fully blinded to group allocation throughout the study. The allocation code will be broken only after data collection is completed and with approval from the ethics committee. This method ensures full allocation concealment and minimizes the risk of selection bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will employ a double-blind design. Participants, clinical care providers, investigators, outcome assessors, and data analysts will all be blinded to group allocation. The ginger supplement and placebo will be identical in appearance, smell, packaging, and labeling, and will be distributed in opaque, sealed, and sequentially numbered envelopes. The clinical officer responsible for dispensing the envelopes will not be involved in any aspect of participant assessment, data collection, or analysis. Outcome assessors and laboratory personnel will receive samples and questionnaires labeled only with participant codes, with no indication of intervention status. Data analysts will work with anonymized datasets that contain no allocation information. Unblinding will occur only after completion of data collection and with approval from the ethics committee. This procedure ensures full blinding of all key study personnel and minimizes performance and detection bias.

Placebo

Used

Assignment

Parallel

Other design features

Participants in the intervention group will receive 2 tablets of 500 mg ginger powder daily for 12 weeks. Participants in the control group will receive 2 tablets of 500 mg cornstarch as placebo daily for the same 12-week period. Since the practical recommendation in the present study is to use ginger powder as a culinary spice, participants will be instructed to take one of the two daily tablets with each of the main meals, namely lunch and dinner.The physical characteristics of the ginger and placebo tablets, including size, shape, and color, will be identical. Additionally, a very small amount of ginger powder will be added to each bottle of placebo tablets to ensure that the odor matches that of the ginger tablet bottles. It should be noted that both ginger and placebo tablets used in this study will be provided by Dineh Iran Industrial Complex. According to the manufacturer, each 500 mg ginger tablet contains the equivalent of 5 mg of ginger essential oil, including active compounds such as

terpenes and phenolic compounds. Each 500 mg ginger tablet is standardized to contain 25 mg of gingerol.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Scien

Street address
Hezarjarib St., school of Pharmacy and Pharmaceutical Sciences, Isfahan, Iran

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Approval date
2026-04-06, 1405/01/17

Ethics committee reference number
IR.MUI.PHANUT.REC.1405.014

Health conditions studied

1

Description of health condition studied
Parkinson’s disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Change in Parkinson’s disease severity based on the total score of the Movement Disorder Society Unified Parkinson’s Disease Rating Scale

Timepoint
Assessment of Parkinson’s disease severity at baseline before the start of the intervention and at the end of week twelve after completion of the intervention

Method of measurement
Movement Disorder Society Unified Parkinson’s Disease Rating Scale

Secondary outcomes

1

Description
Change in serum level of Superoxide dismutase

Timepoint
Measurement of serum Superoxide dismutase at baseline before the start of the intervention and at the end of week twelve of the intervention

Method of measurement
Measurement of serum Superoxide dismutase using standard biochemical methods

2

Description
Change in serum level of Glutathione peroxidase

Timepoint
Measurement of serum Glutathione peroxidase at baseline before the start of the intervention and at the end of week twelve of the intervention

Method of measurement
Measurement of serum Glutathione peroxidase using standard biochemical methods

3

Description
Change in serum total antioxidant capacity

Timepoint
Measurement of serum total antioxidant capacity at baseline before the start of the intervention and at the end of week twelve of the intervention

Method of measurement
Measurement of serum total antioxidant capacity using standard biochemical methods

4

Description
Change in serum total oxidant status

Timepoint
Measurement of serum total oxidant status at baseline before the start of the intervention and at the end of week twelve of the intervention

Method of measurement
Measurement of serum total oxidant status using standard biochemical methods

5

Description
Change in quality of life in patients with Parkinson’s disease

Timepoint
Assessment of quality of life in patients with Parkinson’s disease at baseline before the start of the intervention and at the end of week twelve of the intervention

Method of measurement
Parkinson’s disease quality of life questionnaire

Intervention groups

1

Description
Intervention group: Participants in the intervention group

will receive two 500 milligram tablets containing standardized ginger powder daily for twelve weeks. Each tablet contains 500 milligrams of standardized ginger powder, equivalent to 25 milligrams of active gingerol. The tablets should be consumed with one of the main meals, either lunch or dinner. The ginger tablets are manufactured by Dineh Iran Industrial Complex and have been matched in size, shape, color, and smell with the placebo tablets.

Category
Treatment - Drugs

2

Description
Control group: Participants in the control group will receive two 500 milligram tablets containing corn flour as a placebo daily for twelve weeks. The placebo tablets have been matched in size, shape, color, and smell with the ginger tablets to ensure that participants and researchers remain blinded to group allocation.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Parkinson and Alzheimer Charity Association

Full name of responsible person
Ahmad Chitsaz

Street address
No. 176, End of Alley 1 (Shahid Ramazanpour), Janbazan Street, Se Rah Simin, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Grant name
685,800,000

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
Maziar Ghasemi

Position
Ongoing Master student of Nutrition Sceince

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

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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
De-identified Individual Participant Data (IPD), study protocol, statistical analysis plan (SAP), informed consent form, statistical analysis codes, and data dictionary. These materials include de-identified participant-level data, the final protocol, SAP, shareable informed consent form, analysis scripts (without raw data), and the coding structure used in the study. All IPD will be provided only in fully anonymized form.
When the data will become available and for how long
Data and documents will be available starting 6 months after publication of the primary results and will remain accessible for at least 5 years thereafter.
To whom data/document is available
Qualified researchers affiliated with academic, clinical, or recognized research institutions may request access.
Under which criteria data/document could be used
Data may be used only for valid scientific research and secondary analyses. Applicants must: Submit a clear research proposal Sign a data use and confidentiality agreement Agree not to re-identify participants or share the data with others.
From where data/document is obtainable
Name: Maziar Ghasemi Faculty: School of Nutrition and Food Sciences University: Isfahan University of Medical Sciences, Hezarjarib St., Isfahan, Iran Email: maziar_gh@nutr.mui.ac.ir Alternative email: Maziar.dietitian@gmail.com Phone (optional): +98 921 844 8305
What processes are involved for a request to access data/document
Within 2–4 weeks after receiving a request: The research proposal is reviewed by the study team Ethical compatibility is assessed A Data Use Agreement must be signed De-identified data are prepared and shared via a secure platform
Comments
Additional supporting documents may be provided upon justified request.