

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Mediterranean diet on severity of disease and serum Total Antioxidant Capacity (TAC) in patient with Parkinson's disease

Protocol summary

Study aim

The aim of this study was to determine the effect of the Mediterranean diet on disease severity and total antioxidant capacity in patients with Parkinson disease

Design

Clinical trial, randomized, parallel study

Settings and conduct

80 patients with Parkinson's disease referred to Neurology clinic of Al-Zahara hospital in Isfahan were selected and randomly assigned to two experimental and control groups. Patients in the experimental group receive Mediterranean diet for 10 weeks the control group received no intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: idiopathic Parkinson's disease (based on the criterion (H & Y); ages 40 and older. Exclusion criteria: psychological problems (cognitive problems); failure to complete the consent form; failure to follow the Mediterranean diet and mortality during the intervention period.

Intervention groups

Patients with Parkinson's disease are randomly assigned to experimental and control groups. Patients in the experimental group receive the Mediterranean diet for 10 weeks. No control is conducted in the control group.

Main outcome variables

Effect of Mediterranean diet on disease severity using the Unified Parkinson Disease Rating Scale (UPDRS) scale and total antioxidant capacity (TAC) serum is checked.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141108019853N4**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **retrospective**

Last update: **2018-12-05, 1397/09/14**

Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Zamzam Paknahad

Name of organization / entity

Isfahan University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-04-30, 1396/02/10

Expected recruitment end date

2017-05-20, 1396/02/30

Actual recruitment start date

2017-04-30, 1396/02/10

Actual recruitment end date

2017-05-20, 1396/02/30

Trial completion date

2017-07-19, 1396/04/28

Scientific title

The effect of Mediterranean diet on severity of disease and serum Total Antioxidant Capacity (TAC) in patient with Parkinson's disease

Public title

Effect of Mediterranean diet in Parkinson disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Cases of idiopathic Parkinson's disease (based on criteria (H & Y) Age of illness over 40 years

Exclusion criteria:

Mental illness (cognitive problems) Failure to complete the consent form Failure to follow the Mediterranean diet during the intervention period Death

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with random numbers extracted from the statistical software excel

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collection team and those who evaluate the outcome were kept blind in the study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib, Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2016-05-04, 1395/02/15

Ethics committee reference number

IR.MUI.REC.1395.3.735

Health conditions studied

1

Description of health condition studied

Parkinson disease

ICD-10 code

G20

ICD-10 code description

Hemiparkinsonism Paralysis agitans Parkinsonism or Parkinson disease: NOS idiopathic primary

Primary outcomes

1

Description

Unified Parkinson Disease Rating Scale

Timepoint

Before and after intervention

Method of measurement

Questionnaire

2

Description

Total Antioxidant Capacity (TAC)

Timepoint

Before and after intervention

Method of measurement

ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:Patients in the experimental group receive Mediterranean diet for 10 weeks.

Category

Lifestyle

2

Description

Control group: In the control group received no intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology clinic of Al-Zahara hospital in Isfahan

Full name of responsible person

Dr Ahmad Chitsaz

Street address

Safeh Boulevard - Al-Zahra Educational Center

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Esfahan

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Web page address<http://alzahra.mui.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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Web page address<http://research.mui.ac.ir>**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

Dr Zamzam Paknahad

Position

Ph.D of Nutrition Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available