

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect evaluation of diet with different protein distribution on motor function and serum proteins of patients with Parkinson in Esfahan.

Protocol summary

Study aim

1) Achieve a balanced diet for patients with Parkinson disease. 2) Achieve the proper intake way of protein and the right time to use protein substances in order to avoid interference with Levodopa. And also help patients to improve. 3) Eliminate the limitations in order to increase drugs effect and patients amelioration.

Design

The clinical trial conducted with two groups, the control, and parallel, blind and randomized group. The total sample size is 34 which was equally divided into two groups.

Settings and conduct

The location of the study is Alzahra hospital in Isfahan, after selection of patients, all of the required blood tests will be taken and the diet questionnaire will be completed. The primary evaluation of patients based on UPDRS index and they will be divided into control and intervention group by randomized sampling. After all, the expected diet will be determined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Staphylococcus aureus 3-1 without another neurological disease. Exclusion criteria: Patients with secondary Parkinson disease following usage of antipsychotics, patients with hypothyroidism, patients with fetal bone marrow syndrome, those with BMI less than 18.5 and patients whose serum albumin, pre-albumin and serum homocysteine are below the normal threshold and those who follow a particular diet.

Intervention groups

Intervention group: Protein intake of the intervention group reduced to 10%. Overall protein intake divided into 30% throughout the day and 70% in the dinner meal. Control group: The protein intake is reduced to 10% and is consumed without time constraints overnight

Main outcome variables

Reduction of motor disorders and changes in patient's serum proteins.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180203038593N1**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **prospective**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

hossein khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5752 2676

Email address

khalilyhosien@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect evaluation of diet with different protein distribution on motor function and serum proteins of patients with Parkinson in Esfahan.

Public title

Effect evaluation of diet with different protein distribution on motor function and serum proteins of patients with Parkinson in Esfahan.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patients with Parkinson disease which are at stage 1 to 3 without any other neurological disease.

Exclusion criteria:

The patients with secondary Parkinson disease following antipsychotic drugs. Patients with hypothyroidism. Patients with fetal bone syndrome. Patients with BMI less than 18.5. Patients with serum albumin, pre-albumin and serum homocysteine under the normal threshold. Patients with special food diet and people who opt out of the study. Patients who avoided to participate in the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample randomization of patients and divided them into two groups of control and intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The information of patients will be encoded and the participants will be randomly blinded without knowing the group in which they are located.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Shohadaye gomnam blvd., Aalam sq.

City

Yazd

Province

Yazd

Postal code

8571113741

Approval date

2617-12-20, 1996/09/29

Ethics committee reference number

IR.SSU.SPH.REC.1396.132

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

Motor disfunction

Timepoint

beginning of the study - end of the study

Method of measurement

Unified Parkinson's Disease Rating Scale (UPDRS)

2

Description

Serum proteins

Timepoint

beginning of the study - end of the study

Method of measurement

Blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Protein intake of the intervention group reduced to 10%. Overall protein intake divided into 30% throughout the day and 70% in the dinner meal.

Category

Lifestyle

2

Description

Control group: The protein intake is reduced to 10% and is consumed without time constraints overnight.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Ahmad Chitsaz

Street address

Alzahra Hospital., Soffeh Blvd., Isfahan.

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Province

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Postal code

8174675731

Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology of Yazd
University of Medical Sciences

Street address

Yazd University of Medical Sciences., Shohadaye
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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Hossein khalili

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

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Associate Professor

Latest degree

Ph.D.

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Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Hossein khalili

Position

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Latest degree

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Other areas of specialty/work

Public Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The final report of the study will be shared by regional and foreign journals.

When the data will become available and for how long

Since June 2019

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Academic research and knowledge development

From where data/document is obtainable

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khalilyhosien@yahoo.com

What processes are involved for a request to access data/document

Sending requests through email

Comments