Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 3-1without 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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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 Gomnam Blvd.
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Email
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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

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Person responsible for updating data

Contact

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Student

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
Corresponding author: Hossein Khalili +989139748021 khalilyhosien@yahoo.com

What processes are involved for a request to access data/document
Sending requests through email

Comments