

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of nicotine rich diet with / without redistribution of dietary protein on motor indices in patients with Parkinson's disease

Protocol summary

Study aim

The effect of nicotine rich diet with / without redistribution of dietary protein on motor indices in patients with Parkinson's disease

Design

Clinical trial with control group with parallel group and Randomized on 45 patients.

Settings and conduct

Sampling in this study will be done in several centers in Sari. The 45 patients will be divided into three groups by block randomization. 1) Nicotine rich diet 2) Nicotine rich diet group with redistribution of protein intake 3) Control group. The duration of the intervention is 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parkinson's patients who are over 50 years old and have been diagnosed with Parkinson's disease according to the MDS clinical diagnostic criteria for Parkinson's disease; Patients receiving dopaminergic therapy who have reached a stable dose to control symptoms; Patients who have signed the consent form. Exclusion criteria: Severe systemic or psychological disease; History of gastrointestinal bleeding; Taking aspirin with a dose of more than 325 mg per day; Taking drugs that increase insulin sensitivity, heparin, warfarin, or other anticoagulants and antiplatelets; Exposure to cigarette smoke; Alcohol consumption.

Intervention groups

1) Nicotine rich diet 2) Nicotine rich diet group with redistribution of protein intake 3) Control group

Main outcome variables

Evaluation of disease severity from the Unified Parkinson's Disease Rating Scale (UPDRS); Serum alpha-synuclein protein; Serum apolipoprotein A1; Serum cotinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210618051612N1**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**

Update count: **0**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Hamid Lorvand Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8860 7127

Email address

lorvandhamid@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nicotine rich diet with / without redistribution of dietary protein on motor indices in patients with Parkinson's disease

Public title

The effect of nicotine on Parkinson's disease.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Parkinson's patients who have been diagnosed with Parkinson's disease according to the MDS clinical diagnostic criteria for Parkinson's disease Age over 50 years old Patients receiving dopaminergic therapy who have reached a stable dose to control symptoms Patients who have signed the consent form

Exclusion criteria:

Severe systemic or psychological disease History of gastrointestinal bleeding Taking aspirin with a dose of more than 325 mg per day Taking drugs that increase insulin sensitivity, heparin, warfarin or other anticoagulants and antiplatelets Exposure to cigarette smoke Alcohol consumption

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use block randomization. The blockage is usually used to balance the number of samples allocated to each of the studied groups. All blocks are the same size. Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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-
Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods
St.,Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-06-16, 1400/03/26

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.290

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**

Evaluation of disease severity from the Unified
Parkinson's Disease Rating Scale (UPDRS)

Timepoint

At the beginning and end of the study

Method of measurement

Evaluation of disease severity from the Unified
Parkinson's Disease Rating Scale (UPDRS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The duration of the intervention is 12 weeks. The nicotine-rich group will receive 20 micrograms of nicotine per day through diet.

Category
Treatment - Other

2

Description
Control group: The control group will receive an isocaloric diet.

Category
N/A

3

Description
Intervention group: In this study, the Nicotine-rich diet with protein redistribution group will receive 20 micrograms of nicotine per day through the diet. In this group, 10 grams of protein will be consumed daily until the evening snack. After the evening meal, one gram of protein will be consumed per kilogram of body weight.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali Sina hospital

Full name of responsible person

Hamid Lorvand Amiri

Street address

Sari, Pasdaran Blvd, buali Sina Hospital,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Mohammadhasan Javanbakht

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Doctor Mohammadhasan Javanbakht

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Hamid Lorvand Amiri

Position

Ph.D student.

Latest degree

Master

Other areas of specialty/work

Nutrition

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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