

# 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,

**City**

Sari

**Province**

Mazandaran

**Postal code**

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**Fax****Email**

starnba5532@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Doctor Mohammadhasan Javanbakht

**Street address**

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tumspr@tums.ac.ir

**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****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 updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**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