Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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Email address
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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 iscaloric 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
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Sari, Pasdaran Blvd, buali Sina Hospital,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Other areas of specialty/work
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Person responsible for updating data

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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