Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluating the effect of intranasal insulin administration on motor and non-motor symptoms in Parkinson’s disease patients; a randomized double-blinded placebo-controlled clinical trial

Protocol summary

Study aim

1. Evaluating the effect of intranasal insulin on motor symptoms of Parkinson’s disease 2. Evaluating the effect of intranasal insulin on non-motor symptoms of Parkinson’s disease

Design

This study is a single-center, parallel and double-blind study. Patients, researchers (physicians, outcome assessors) and data analysts are blinded. Patients with Parkinson's disease referred to Motor Movement Clinic of Shohadaye Tajrish Hospital are randomly divided into control and treatment groups.

Settings and conduct

Patients with Parkinson's disease referred to Motor Movement Clinic of Shohadaye Tajrish Hospital are randomly received intranasal placebo or insulin, every day, twice a day for 6 weeks. Motor and non-motor symptoms of patients are evaluated during the study in four times; baseline, 4, 8 and 12 weeks after treatments. Primary outcome is motor symptoms, and secondary outcomes including symptoms cognitive, memory, sleep disorders, depression, heart rate and postural hypertension).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Man and woman over 17 years old; Patient with Parkinson's disease according to UKPDSBB criteria; Patients with written informed consent. Exclusion criteria: Pregnant and lactating women; Patients with diabetes and taking anti-hyperglycemic drugs; Patients with other neurodegenerative diseases like multiple system atrophy, Huntington's, Wilson's disease, Alzheimer's, ALS, progressive supranuclear palsy, etc.; Patients who cannot walk for more than one minute without help; A history of allergic reaction to insulin; The presence of inflammation of nasal cavity.

Intervention groups

Control (placebo) and insulin groups

Main outcome variables

Score of motor symptoms at Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) questionnaire (Part III, IV)

General information

Reason for update

1- The phase of the study has been written as phase 3, thus it was been changed. 2- The duration of study was changed from 6 weeks to 12 weeks, and follow up duration was changed from every two weeks to every four weeks. 3- The study has been registered in WWW.clinicaltrials.gov, therefore, its information has added to the profile.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045196N1**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **1**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Neda Valian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01
Expected recruitment end date
2022-01-21, 1400/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of intranasal insulin administration on motor and non-motor symptoms in Parkinson’s disease patients; a randomized double-blinded placebo-controlled clinical trial

Public title
Evaluating the effect of intranasal insulin administration on motor and non-motor symptoms in Parkinson’s disease patients; a randomized double-blinded placebo-controlled clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Man and woman over 17 years old Patient with Parkinson's disease according to UKPDSBB criteria Provide written informed consent to participate in the study Understand that they may withdraw their consent at any time.
Exclusion criteria:
1. Pregnant and lactating women 2. Patients with diabetes and taking anti-hyperglycemic drugs 3. Other neurodegenerative diseases like multiple system atrophy, Huntington's, Wilson's disease, Alzheimer's, ALS, progressive supranuclear palsy, etc. 4. Patients who cannot walk for more than one minute without help. 5. Patients with history of allergic reactions to insulin 6. Patients with history of nasal cavity inflammation that prevents insulin absorption 7. Patients with kidney and liver diseases
Age
From **17 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients, researchers (physicians, outcome assessors) and data analysts are not aware about prescribed drugs.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
مرکز ثبت کارآزمائي هاي باليني ايالات متحده آمريکا (www.clinicaltrial.gov)
Secondary trial Id
NCT04687878
Registration date
2020-12-29, 1399/10/09

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Public Health and Neuroscience Research Center, Shahid Beheshti Univer
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School of Public Health and Neuroscience Research Center, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Yaman Ave., Shahid Chamran Exp., Tehran, Iran
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Province
Tehran
Postal code
1983963113
Approval date
2019-10-08, 1398/07/16
Ethics committee reference number
IR.SBMU.PHNS.REC.1398.094

Health conditions studied

1

Description of health condition studied
Parkinson's disease
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score of motor symptoms
Timepoint
Motor symptoms score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) questionnaire (Part III, IV)

Secondary outcomes

1

Description
Score of non-motor symptoms
Timepoint
Non-motor symptoms score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) questionnaire (Part I, II)

2

Description
Score of depression
Timepoint
Depression score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Beck's Depression Inventory II questionnaire

3

Description
Score of anxiety
Timepoint
Anxiety score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Beck Anxiety Inventory (BAI) questionnaire

4

Description
Score of fatigue severity
Timepoint
fatigue score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Fatigue Severity Scale (FSS) questionnaire

5

Description
Score of disease severity
Timepoint
severity score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Modified Hoehn and Yahr (HY) questionnaire

6

Description
Score of cognitive symptoms
Timepoint
Cognitive symptoms score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Montreal Cognitive Assessment (MOCA) questionnaire

7

Description
Score of cognitive symptoms
Timepoint
Cognitive symptoms score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Scales for Outcomes of Parkinson’s disease-cognition (SCOPA-COG) questionnaire

8

Description
Score of Falling
Timepoint
Falling score at the base line (before initiation the intervention) and 4, 8 and 12 weeks after intervention
Method of measurement
Tinetti Balance Assessment Tool questionnaire

Intervention groups

1

Description
Control group: Placebo, intranasal administration, every day, twice a day, in both sides, for 12 weeks
Category
Behavior

2

Description
Intervention group: Insulin, intranasal administration, 40 IU/day, every day, twice a day, in both sides, for 12 weeks
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Mehri Salari
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Shohadaye Tajrish Educational Hospital, Tajrish Square, Tehran Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Dargahi
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehri Salari
Position
Assistant professor
Latest degree
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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