Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effect of Lisdexamfetamine versus Placebo on the Severity and Frequency of Freezing of Gait (FOG) in the ON Phase in Patients with Parkinson’s Disease

Protocol summary

Study aim

Evaluation of the Effect of Lisdexamfetamine on Freezing of Gait in Patients with Parkinson’s Disease”

Design

Randomized, controlled clinical trial with parallel groups, single-blind

Settings and conduct

A total of 90 patients with idiopathic Parkinson’s disease who attend the Movement Disorders Clinic of Rasoul Akram Hospital and experience varying degrees of freezing of gait (FOG) during the ON phase will be included.The sampling method will be convenience sampling, and patients will be randomly assigned to two study groups.completion of the FOG questionnaire before and after the intervention will be performed by a movement disorders fellowship.

Participants/Inclusion and exclusion criteria

1.Diagnosis of idiopathic Parkinson’s disease confirmed by a movement disorders (Parkinson’s) fellowship-trained neurologist.2.History of freezing of gait episodes, with a baseline FOG score ≥ 10.3.Age between 40 and 80 years. 4.Stable treatment regimen with no medication changes within the past 1 month.5.Receiving a stable dose of levodopa for the past 4 weeks. 6.Provision of written informed consent to participate in the study. 1.Severe psychiatric disorders2.Severe cardiovascular diseases 3.Use of other central nervous system stimulants.4.Severe cognitive impairment, defined as MMSE < 24.5.Development of severe adverse events requiring discontinuation of the study medication.6.History of hypersensitivity to psychostimulants.

Intervention groups

Group 1 (45 patients): will receive Lisdexamfetamine 30 mg once daily for a duration of 6 weeks. Outcome questionnaires will be completed again at the end of the 6-week treatment period. Group 2 (45 patients): will receive a placebo for 6 weeks, and the same questionnaires will be completed before and after the 6-week placebo period.

Main outcome variables

severity of freezing of gait (FOG score);Change in FOG score after 6 weeks of

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251122068081N1**
Registration date: **2025-12-16, 1404/09/25**
Registration timing: **prospective**

Last update: **2025-12-16, 1404/09/25**
Update count: **0**

Registration date

2025-12-16, 1404/09/25

Registrant information

Name

neda sheikhinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3663 0667

Email address

neda.sheikhinia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Lisdexamfetamine versus Placebo on the Severity and Frequency of Freezing of Gait (FOG) in the ON Phase in Patients with Parkinson’s Disease

Public title

Evaluation of the Effect of Lisdexamfetamine on Freezing of Gait in Patients with Parkinson’s Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of idiopathic Parkinson’s disease confirmed by a movement disorders (Parkinson’s) fellowship. History of freezing of gait episodes, with a baseline FOG score ≥ 10. Age between 40 and 80 years Stable treatment regimen with no medication changes within the past 1 month. Receiving a stable dose of levodopa for the past 4 weeks. Provision of written informed consent to participate in the study.

Exclusion criteria:

Severe psychiatric disorders, such as schizophrenia or bipolar disorder Severe cardiovascular diseases, including uncontrolled heart failure. Use of other central nervous system stimulants Severe cognitive impairment, defined as MMSE < 24. Development of severe adverse events requiring discontinuation of the study medication History of hypersensitivity to psychostimulants. Presence of comorbid conditions that may impair gait, such as stroke or significant osteoarthritis.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

placebo group using block randomization with variable block sizes of 4 and 6 to ensure balanced allocation. Individual randomization will be applied, and stratified randomization based on baseline FOG severity (FOG score 10–20 vs. >20) will be used to minimize imbalance between groups.The randomization sequence will be generated by an independent statistician using IBM SPSS. Allocation assignments will be placed in sealed, opaque, sequentially numbered envelopes, which will be opened by the study coordinator only after enrollment and consent.The medication and placebo will be prepared in identical packaging so that only the participant remains blinded to group allocation. Investigators and outcome assessors will be aware of the assigned intervention; therefore, the study will follow a single-blind (participant-blind) design.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single-blind (Single-Blind) trial, meaning that only the participants are unaware of their assignment to either the 4-aminopyridine or placebo group. Participants: Blinded; the study drug and placebo are provided in identical packaging to prevent any discernible differences. Principal investigator and treating physicians: Not blinded, due to the need for monitoring potential drug-related adverse effects. Nurses, physiotherapists, and pharmacist: Not blinded; they are responsible for administering the study medication or patient care, but the allocation information is not disclosed to the participants. Outcome assessors and data collectors: Not blinded, but they follow standardized protocols to minimize bias. Data Safety and Monitoring Committee (DSMC): Not blinded, as they are responsible for reviewing patient safety. Data analysts and manuscript writers: Analysts remain blinded until the completion of the analysis, with groups coded as A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of iran University of Medical Sciences

Street address

Hazrat Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-10-13, 1404/07/21

Ethics committee reference number

IR.IUMS.FMD.REC.1404.467

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
Severity of freezing of gait (FOG score) as measured by the FOG Questionnaire;
Timepoint
The FOG questionnaire will be completed at baseline and again 6 weeks after initiating the study medication.
Method of measurement
FOG questioner

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Lisdexamfetamine 30 mg, taken once daily for 6 weeks
Category
Treatment - Drugs

2

Description
Control group: placebo taken once daily for 6
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
neda sheikhinia
Street address
Hazrat Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1000
Email
neda.sheikhinia@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
neda sheikhinia
Street address
Hazrat Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1000
Email
neda.sheikhinia@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
neda sheikhinia
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
Street address
Hazrat Rasoul Akram Hospital, Niayesh Street,

Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1000
Email
neda.sheikhinia@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
neda sheikhinia
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
Street address
Hazrat Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1000
Email
neda.sheikhinia@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
neda sheikhinia
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
Street address
Hazrat Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1000
Email
neda.sheikhinia@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
Information related to the primary outcome can be shared
When the data will become available and for how long
Access period starts 6 months after the publication of results
To whom data/document is available
Researchers affiliated with academic and scientific institutions
Under which criteria data/document could be used
Use of data for completing clinical studies
From where data/document is obtainable
Rasoul Akram Hospital
What processes are involved for a request to access data/document
Upon review of the researcher’s request and submission of sufficient documentation about their study and the rationale for using the data, access may be granted
Comments