# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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
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**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
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## 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**