

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Determining and comparing the effect of 4-aminopyridine 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

Determination and Comparison of the Effect of 4-Aminopyridine versus Placebo on the Severity and Frequency of Freezing of Gait (FOG) in the on Phase in Patients with Parkinson's Disease Referred to Rasoul Akram Hospital, Tehran.

Design

a randomized, controlled clinical trial with parallel groups, single-blind (participants only), phase 2, conducted on 90 patients with Parkinson's disease experiencing episodes of freezing of gait (FOG). Participants will be divided into two groups with 45 patients each. Randomization will be performed using the RAND function in Microsoft Excel.

Settings and conduct

Patient referral to Movement Disorders Clinic / clinical examination and completion of questionnaires and informed consent / medication prescription using a single-blind design, meaning that only the participants are unaware of their allocation to either the 4-aminopyridine group or the placebo group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Diagnosis of idiopathic Parkinson's disease confirmed by a Parkinson's disease fellowship. 2. History of experiencing episodes of freezing of gait, with a baseline FOG score ≥ 10 . 3. Age between 40 and 80 years. 4. Providing written informed consent to participate in the study. Exclusion Criteria: 1. History of hypersensitivity to 4-aminopyridine. 2. History of seizures for any reason. 3. Occurrence of severe adverse effects requiring discontinuation of the medication.

Intervention groups

A total of 45 patients will receive 4-aminopyridine 10 mg every 12 hours for a duration of 6 weeks, after which the questionnaires will be completed again. Another 45 patients will receive placebo, and the questionnaires will be filled out for them before and after 6 weeks of

placebo administration.

Main outcome variables

Severity of freezing of gait (FOG score); Frequency of freezing of gait episodes; Change in FOG score after 6 weeks of treatment;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251122068081N2**

Registration date: **2025-12-20, 1404/09/29**

Registration timing: **prospective**

Last update: **2025-12-20, 1404/09/29**

Update count: **0**

Registration date

2025-12-20, 1404/09/29

Registrant information

Name

neda sheikhinia

Name of organization / entity

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Iran (Islamic Republic of)

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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

Determining and comparing the effect of 4-aminopyridine 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 4-aminopyridine 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 Parkinson's disease fellowship-trained neurologist
History of experiencing episodes of freezing of gait, with a baseline FOG score ≥ 10 Age between 40 and 80 years
Stable treatment regimen with no medication changes during the past month Receiving a stable dose of levodopa for the past 4 weeks Providing written informed consent to participate in the study.

Exclusion criteria:

History of hypersensitivity to 4-aminopyridine. History of seizures for any reason. Presence of severe cognitive impairment (MMSE < 24). Presence of another comorbidity that can impair gait, such as stroke or osteoarthritis Occurrence of severe adverse effects requiring discontinuation of the medication.

AgeFrom **40 years** old to **80 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant

Sample sizeTarget 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)

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

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Niayesh St, Satarkhan St, Tehran, Iran

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1449614535

Approval date

2025-08-12, 1404/05/21

Ethics committee reference number

IR.IUMS.FMD.REC.1404.249

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.(this variable reflects the intensity of FOG episodes and will be used to assess the effect of 4-aminopyridine compared to placebo)

Timepoint

questionnaire completed before and after the 6-week treatment.

Method of measurement

freezing of gait (FOG)Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 4-Aminopyridine 10 mg (Dalfyra®, Arvand Pharmed) is prescribed at a dose of one tablet every 12 hours for 6 weeks. Each patient is provided with 84 tablets of Dalfyra® 10 mg to be taken over a period of 6 weeks, at a dosage of two tablets per day, administered at 12-hour intervals.

Category

Treatment - Drugs

2**Description**

Control group :Placebo(vit b1300) taken Q12 h for 6 weeks. Each patient is provided with 84 tablets of Placebo over a period of 6 weeks, at a dosage of two tablets per day, administered at 12-hour intervals.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital, Tehran – Movement Disorders Clinic

Full name of responsible person

Fahimeh mohaghegh

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

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

Iran University of Medical Sciences

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

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

Fahimeh mohaghegh

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Fahimeh mohaghegh

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

You may request an appointment by visiting the Movement Disorders Clinic at Rasoul Akram Hospital or by emailing: fahmoh2013@gmail.com

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