

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the effects of Fampridine (4-aminopyridine) on motor and non-motor symptoms of Parkinson: A randomized double blind trial

Protocol summary

Study aim

Determining the effect of Fampridine (4-aminopyridine) on motor and non-motor symptoms of Parkinson's disease in patients referred to the neurology clinic.

Design

Clinical trial with intervention and control group, with parallel groups, double-blind, randomized, phase 3 on 62 patients. For randomization, block random assignment and the order of assigning each person to each group in a sealed envelope was used.

Settings and conduct

The study will be conducted on Parkinson patients referred to Shahr-e-Kord Neurology Clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: known Parkinson's patient (based on symptoms and previous investigations); the presence of Parkinson's symptoms in the patient; the symptoms are not caused by other diseases (such as stroke, trauma, etc.); no interaction with other drugs; no history of seizures. Exit criteria: unwillingness to cooperate; intervention drug interaction with usual drugs; occurrence of drug side effects; intensification of the patient's symptoms; death of the patient history or occurrence of seizures.

Intervention groups

One group will receive Fampridine tablets (Cinagen Pharmaceutical Company) as the intervention group, and the other group will receive placebo as the control group, and both groups will receive their standard treatment.

Main outcome variables

tremor condition; Brady Kinsey's situation; the state of rigidity; sleep disorder condition; Depressive state; state of anxiety; sexual disorder status; sphincter disorder condition; paresthesia condition of organs; Hypotension orthostatic state; General condition of motor and non-motor disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230905059361N1**

Registration date: **2023-10-03, 1402/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-03, 1402/07/11**

Update count: **0**

Registration date

2023-10-03, 1402/07/11

Registrant information

Name

Mohammad Shams

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3257 9932

Email address

mohammadsh3428@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2023-10-21, 1402/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Fampridine (4-aminopyridine) on motor and non-motor symptoms of Parkinson: A randomized double blind trial	
Public title	Fampridine effect on Parkinson disease symptoms
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Known Parkinson's disease presence of Parkinson's symptoms in the patient The symptoms are not due to other diseases (such as stroke, trauma, etc.) No interaction with other drugs No history of seizures Exclusion criteria: Reluctance to cooperate Interference of the intervention drug with usual drugs Aggravation of the patient's symptoms History or occurrence of seizures
Age	No age limit
Gender	Both
Phase	3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 62
Randomization (investigator's opinion)	Randomized
Randomization description	In order to start the clinical trial study, with the coordination of the supervisor, 62 patients will be randomly selected from among the patients who meet the entry criteria referring to the neurology clinic, according to the sample size if they meet the entry criteria. Then, people will be assigned to two equal intervention and control groups using the random block allocation method with blocks of 2, 4, and 6, and the order of assigning each person to each group is placed in a sealed envelope based on blocks with a random number. The same number of people are assigned to each of the studied groups
Blinding (investigator's opinion)	Double blinded
Blinding description	The participants do not know whether they are part of the intervention or control group and do not know whether they are taking medicine or placebo. Medicines and placebos are given to patients by clinical caregivers, and the researcher does not know who received medicine or placebos
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of Shahr-e-Kord University of Medical Sciences Street address Rahmatieh City Shahr-e-Kord Province Chahar-Mahal-va-Bakhtiari Postal code 8841646176 Approval date 2023-08-13, 1402/05/22 Ethics committee reference number IR.SKUMS.MED.REC.1402.038
Health conditions studied	1 Description of health condition studied Parkinson disease ICD-10 code G20 ICD-10 code description Parkinson's disease
Primary outcomes	1 Description Motor and non-motor symptoms of Parkinson's disease Timepoint Before and after the start of the intervention Method of measurement Using the MDS-UPDRS questionnaire
Secondary outcomes	empty
Intervention groups	1 Description Intervention group: One group will receive fampridine tablets (Cinagen Pharmaceutical Company) as the intervention group. The new drug will be part of their treatment regimen along with the routine treatment regimen and the new treatment regimen will continue as before. The intervention group will receive fampridine

tablets with a dose of 10 mg twice a day (Cinagen Pharmaceutical Company) for one month, which is currently considered as the duration of the study.

Category

Treatment - Drugs

2

Description

Control group: A group with the same size as the intervention group that receives placebo in the same amount and duration as the intervention group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Mohammad Shams

Street address

Shariati Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Arsalan Khaledifar

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Rahmatieh

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Shams

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree

A Level or less

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The data of the study before and after the intervention are collected and published to check the results of the intervention

When the data will become available and for how long

The access period starts about 6 months after the publication of the study results

To whom data/document is available

Scientific institutions, students, professors, pharmacists, manufacturing companies

Under which criteria data/document could be used

Doctors to use the results of the study in better treatment of the disease Pharmacists for more effort in improving the quality of this drug Professors and students to know more about the effect of this medicine Manufacturing companies to invest in more and better drug production

From where data/document is obtainable

Mohammad Shams Hafshejani Contact: +989136763428
Email: Mohammadsh3428@gmail.com

What processes are involved for a request to access data/document

After contacting the person with the required information and after confirming the validity of the applicant, the method of obtaining the required information will be announced to the applicant within a few days.

Comments