

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Investigating the effect of ondansetron on Levodopa-induced dyskinesia in patients with parkinson's disease

Protocol summary

Study aim

Investigating the effect of ondansetron on Levodopa-induced dyskinesia in patients with Parkinson's disease
Providing scientific evidence regarding the effectiveness of amantadine replacement therapy in controlling levodopa-induced dyskinesia in patients with Parkinson's disease

Design

Phase 3 randomized clinical trial with parallel groups, with a control group, double-blind, will be conducted on 32 patients. For randomization, 16 blocks will be selected using the random number table (blocks of 4) so that the sample size reaches 32 people.

Settings and conduct

The research setting includes the neurology clinic of Vali Asr Medical Training Center in Zanjan and the research community includes all people with levodopa induced dyskinesia who refer to the center. Individuals will be selected by the available method and then randomly assigned to the intervention group, Ondansetron, and the control group, placebo. In this study, doctor and patients will be blinded.

Participants/Inclusion and exclusion criteria

patients can participate in study: People with Parkinson's Stage 3, 4 based on Hoehn and Yahr scale Age over 18 years Having dyskinesia caused by levodopa Patient satisfaction patients must not participate in study: Allergy to ondansetron (rash, itching) Concomitant use of apomorphine in patients in off episodes pregnancy breastfeeding occurrence of any unpredictable complications The patient's unwillingness to continue participating in study

Intervention groups

The intervention group will take ondansetron tablets 8 mg daily orally in the first week and then 12 mg daily (8 mg in the morning and 4 mg at night) from the second to the eighth week for two months and the control group will receive a placebo with the same prescription. Effects will be evaluated at weeks zero, four and eight.

Main outcome variables

levodopa induced dyskinesia 's severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190427043389N5**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Hamed Ghavimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ondansetron on Levodopa-induced dyskinesia in patients with parkinson's disease

Public title

Investigating the effect of ondansetron on Levodopa-induced dyskinesia in patients with parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with Parkinson's disease stages 3, and 4 based on Hoehn and Yahr scale age over 18 years patients with levodopa induced dyskinesia Patient satisfaction

Exclusion criteria:

Allergy to ondansetron (rash, itching) Concomitant use of apomorphine in patients with off episodes pregnancy breastfeeding The patient's unwillingness for participation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible people will be selected from the usual referrals to the neurology clinic of Vali Asr Zanjan educational center by the available method and then will be allocated to two groups by random block method (blocks of 4). The first group will receive oral tablets of ondansetron and the second group will receive placebo. For this purpose, blocks of 4 will be selected using a table of random numbers in the size of 16 blocks so that the sample size reaches 32 people. Blocking will be done by a person not involved in sampling. Each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. Finally, the lids of the envelopes will be glued and placed inside a box. At the start of the intervention to identify the order of the participants, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, people will be assigned to two groups by random block method (blocks of 4). Patients will be blinded in this study. One group will receive standard treatment along with ondansetron tablets, while the other group will receive standard treatment along with a

placebo. Placebo tablets are very similar to ondansetron tablets in terms of color, shape and size, but do not contain the active drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Zanjan University of Medical Science

Street address

Jomhuri Street, Azadi Boulevard, University Headquarters, 1st floor, Deputy of Research and Technology, Zanjan University of Medical Science

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Zanjan

Province

Zanjan

Postal code

451561391

Approval date

2023-10-31, 1402/08/09

Ethics committee reference number

IR.ZUMS.REC.1402.205

Health conditions studied**1****Description of health condition studied**

levodopa-induced dyskinesia

ICD-10 code

G21.11

ICD-10 code description

Neuroleptic induced parkinsonism

Primary outcomes**1****Description**

Levodopa induced dyskinesia score in Unified Dyskinesia Rating Scale questionnaire

Timepoint

Before intervention, one and two months after starting intervention

Method of measurement

Unified Dyskinesia Rating Scale questionnaire

Secondary outcomes

1

Description

Levodopa-induced dyskinesia 's severity

Timepoint

Before starting intervention, one and two months after starting intervention

Method of measurement

Unified Dyskinesia Rating Scale questionnaire

Intervention groups

1

Description

Intervention group: will take ondansetron tablets in the form of 8 mg daily orally in the first week and then in the form of 12 mg daily (8 mg in the morning and 4 mg at night) from the second to the eighth week for two months.

Category

Treatment - Drugs

2

Description

Control group: will receive the placebo in the order of the first week, two in the morning, and then, from the second to the eighth week, two in the morning and one in the evening.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Neurology clinic

Full name of responsible person

Hamed Ghavimi

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Sheikh fazlolah Nori Ave, Valiasr square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Jomhuri Street, Azadi Boulevard, University Headquarters, 1st floor, Deputy of Research and Technology, Zanjan University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Zanjan University of Medical Science

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

Zanjan University of Medical Sciences

Full name of responsible person

Hamed Ghavimi

Position

academic member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

3 months

To whom data/document is available

Researchers

Under which criteria data/document could be used

A person can access the data after requesting the person in the charge of the trial and checking her reliability.

From where data/document is obtainable

Central Library of Zanjan University of Medical Science

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

A person can access the data after requesting the person in the charge of the trial and checking her reliability.

Comments