Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of Atomoxetine efficacy on Freezing of gait in patient with Parkinson

Protocol summary

Study aim
Evaluation of Atomoxetine efficacy on Freezing of gait in patient with Parkinson referred to Ahvaz golestan hospital in a period six month in 2021

Design
A total of 32 patients of both sexes and all age groups will be randomly selected from Parkinson's patients referred to Ahvaz Golestan Hospital in a period of 6 months in 1400 who had frozen gait. Group A includes 16 patients, which an uninformed person randomly selected.

Settings and conduct
Blinding will be done by recording atomoxetine and placebo by a person who has no information about the patient group. Thirty-two Parkinson's patients referred to Golestan Hospital in Ahvaz for a period of 6 months in 1400 who suffered from frozen gait were randomly selected by an uninformed person and treated with atomoxetine at a dose of 40 mg for 2 weeks and then Dose increases to 80 mg for six weeks.

Participants/Inclusion and exclusion criteria
Entry 1. Diagnosis of Parkinson's disease based on examination and history 2. Patients with stage 2-4 of Hoehn and yahr scale; 3. Normal tests (vitamin B12, thyroid, liver and kidney tests) 4. Levodopa treatment for at least 3 months before the study 5. Ability to walk at least 20 steps without the use of assistive devices No entry 1. Continued use of stimulants (STIMULANT) 2. Contraindications to the use of atomoxetine

Intervention groups
Patient with Parkinson referred to Ahvaz Golestan hospital

Main outcome variables
Age; Gender; Duration of illness; drug side effects; Follow-up time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211008052695N1**
Registration date: **2021-11-17, 1400/08/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-17, 1400/08/26**
Update count: **0**

Registration date
2021-11-17, 1400/08/26

Registrant information

Name
Esmat Ramezanirad

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 3441 0975

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Atomoxetine efficacy on Freezing of gait in patient with Parkinson

Public title

Evaluation of Atomoxetine efficacy on Freezing of gait in patient with Parkinson

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) Diagnosis of Parkinson's disease based on examination and history 2) Patients with stage 2-4 of Hoehn and yahr scale; 3) Normal tests (vitamin B12, thyroid, liver, and kidney tests) 4) Levodopa treatment for at least 3 months before the study 5) Ability to walk at least 20 steps without the use of assistive devices

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized controlled clinical trial. In this study, patients will be assigned to each treatment group using a randomized block method using four blocks in this study. Blocking is used to balance the number of samples assigned to each of the study groups. This feature helps to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The blinding method will also be used to prevent the allocation from being disclosed in each block. This study will be double-blind. The correction will be performed by recording atomoxetine and placebo by a person who has no information about the patient group. A total of 32 patients of both sexes and all age groups were randomly selected from Parkinson's patients referred to Ahvaz Golestan Hospital in 6 months in 1400 who had frozen gait and were treated with levodopa. Hoehn and yahr scale divisions in groups 2 to 4 will be included in the study. Group A consists of 16 patients randomly selected by an uninformed person and treated with atomoxetine 40 mg for two weeks and then increased the dose to 80 mg for six weeks. Group B consists of 16 patients who are randomly selected by an uninformed person and are treated with a placebo similar to group A. The first visit will be on the first day before starting treatment and determining the score of the FOGQ questionnaire and starting the medication. This questionnaire consists of 6 questions, each of which receives a score of 0 to 4, and the minimum score is 0, and the maximum is 24. The second visit will take place two weeks after treatment, and the third visit will take place six weeks after the second visit. The score of the FOGQ questionnaire will be prepared from the patient, and finally, the data will be analyzed by SPSS statistical software version 22. The FOGQ questionnaire is a questionnaire that assesses the freezing of gait in Parkinson's patients. Giladi introduced this questionnaire in 1999. Giladi calculated the validity and reliability of this questionnaire on 40 patients with Parkinson's disease. Using Cronbach's alpha, 94% was obtained, and the validity rate for this questionnaire was 70% (Giladi article reference). In Iran, this questionnaire was translated by Taghizadeh in 2021. He used the questionnaire for 115 patients with Parkinson's disease. Cronbach's alpha was 92% (Taghizadeh article).

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done by recording atomoxetine and placebo by a person who has no information about the patient group. A total of 32 patients of both sexes and all age groups were randomly selected from Parkinson's patients referred to Ahvaz Golestan Hospital in a period of 6 months in 1400 who had frozen gait and were treated with levodopa. The Hoehn and yahr scale divisions in categories 2 to 4 will be included in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Golestan Hospital

Street address

No. 9, 9 Resalat Ave., NIDC Complex

City

ahwaz

Province

Khouzestan

Postal code

6166648791

Approval date

2021-04-13, 1400/01/24

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.026

Health conditions studied

1

Description of health condition studied

Parkinson disease

ICD-10 code

G21.9

ICD-10 code description

Secondary parkinsonism, unspecified

Primary outcomes

1

Description

Freezing of gait in patient with Parkinson

Timepoint

Patients are treated with atomoxetine at a dose of 40 mg for 2 weeks and then increase the dose to 80 mg for six weeks.

Method of measurement

The first visit will be on the first day and before starting treatment, determining the FOGQ questionnaire's score, and starting the medication. This questionnaire consists of 6 questions, each of which receives a score of 0 to 4, and the minimum score is 0, and the maximum is 24. The second visit will take place two weeks after the start of treatment, and the third visit will take place 6 weeks after the second visit.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A includes 16 patients randomly selected by an uninformed person and treated with atomoxetine 40 mg for 2 weeks and then increase the dose to 80 mg for six weeks.

Category

Treatment - Drugs

2

Description

Control group: Group B includes 16 patients who are randomly selected by an uninformed person and are treated with a placebo similar to group A.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Golestan Hospital

Full name of responsible person

Seyed Ehsan Mohamadianinejad

Street address

No. 9, 9 Resalat Ave., NIDC Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Seyed Ehsan Mohamadianinejad

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Farvardin Ave., Golestan Hospital., Golestan

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Seyed Ehsan Mohamadianinejad

Position

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
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
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
After the analysis, the study results are presented to all study participants in the form of a file.
When the data will become available and for how long
Start of the access period from the end of 1400 for 6 months after the end of printing the results
To whom data/document is available
Researchers and participants
Under which criteria data/document could be used
Access to the data is not an obstacle if the participants' personal details are distorted.
From where data/document is obtainable
Responsible person - 09163439107
What processes are involved for a request to access data/document
Contact the project manager - review the application - register and submit
Comments