

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of Ginkgo Biloba efficacy in treatment of drug-induced parkinsonism;; A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Determining the effectiveness of Ginkgo biloba in reducing the severity of Parkinson's motor symptoms (based on UPDRS motor score) Comparison of the degree of change in the severity of drug induced parkinsonism motor symptoms (based on the score of the UPDRS motor department) in patients after the intervention compared to before, between the two groups receiving Ginkgo biloba and placebo Determining the effectiveness of Ginkgo biloba in improving patients' cognition (based on MoCA score) Comparison of cognitive change (based on MoCA score) in patients with drug-induced Parkinsonism after the intervention compared to before, between the two groups receiving Ginkgo biloba and placebo

Design

Clinical trial with control group, double-blind, randomized, phase 2 on 102 patients. Block randomization method (block size of four) is used for randomization.

Settings and conduct

Place of study: Roozbeh hospital, neurology Ward Double blind study method: By an out-of-study researcher

Participants/Inclusion and exclusion criteria

inclusion criteria: all Psychiatric patients suspected of drug induced parkinsonism Non-inclusion criteria: Thrombocytopenia, Coagulopathy, Kidney failure Liver failure, GI bleeding history, Consumption of warfarin, high dose NSAIDs or NSAIDs with SSRIs and CCBs

Intervention groups

Intervention group: Ginkgo biloba 40 mg tablet; 2 tablets every 8 hours for 3 months. Control group: placebo tablet; 2 tablets every 8 hours for 3 months.

Main outcome variables

Severity of motor symptoms; cognition of patients; Quality of life in patients with drug induced parkinsonism.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048060N1**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **prospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Arash Kalantar mehrjardi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2676 9636

Email address

a_kalantarm@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-20, 1401/03/30

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Ginkgo Biloba efficacy in treatment of drug-induced parkinsonism;; A randomized, double-blind, placebo-controlled clinical trial

Public title

Ginkgo Biloba efficacy in treatment of drug-induced parkinsonism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All psychiatric patients with the symptoms of drug induced parkinsonism, who have been given neurological counseling and Parkinson's drug-induced event has been confirmed based on clinical judgments and other findings among them Age over 18 years

Exclusion criteria:

Thrombocytopenia Coagulopathy Kidney failure Liver failure GI bleeding history Consumption of warfarin, high dose NSAIDs or NSAIDS with SSRIs and CCBs.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient randomization is based on simple randomization method. Thus, based on the table of random numbers, even numbers are considered for the Ginkgo receiving group and odd numbers for the placebo receiving group. The statistical software used for randomization is R.

Blinding (investigator's opinion)

Double blinded

Blinding description

One of the out-of-field researchers prepared a random sequence of patients and coding the drug packages of each patient. Drugs and placebo tablets, which are similar in appearance, are taken into similar boxes. All tablets required by each patient are packed in coded boxes during the study period. The patient listing is also provided to the field-based researcher based on these codes. All clinical evaluations will be performed by another researcher in the field who is not involved in the allocation process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

13th floor, block A, Headquarters of the Ministry of Health, Treatment and Medical Education, Simaye-Iran st., between Zarafshan and south Falamak st., Shahrak Qods, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2019-12-19, 1398/09/28

Ethics committee reference number

IR.TUMS.TIPS.REC.1398.119

Health conditions studied

1

Description of health condition studied

drug-induced parkinsonism

ICD-10 code

G21.21

ICD-10 code description

Other drug-induced secondary parkinsonism

Primary outcomes

1

Description

Improving the severity of drug induced parkinsonism symptoms in patients

Timepoint

before intervention and 1 and 3 months after intervention

Method of measurement

Unified Parkinson's Disease Rating Scale (UPDRS) questionnaire Simpson-Angus Extrapyramidal Side Effects Scale (SAS) questionnaire

2

Description

Improving the cognitive function in patients

Timepoint

before intervention and 1 and 3 months after intervention

Method of measurement

MoCA (Montreal Cognitive Assessment) questionnaire

3

Description

improving the quality of life of patients

Timepoint

before intervention and 1 and 3 months after intervention

Method of measurement

PDQ-39 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Ginkgo biloba tablets - 40 mg every 8 hours 2 tablets (daily dose 240 mg) - for 3 months - drug manufacture: tolid darou

Category

Treatment - Drugs

2

Description

Control group: placebo tablets - every 8 hours 2 tablets for 3 months - drug manufacture: tolid darou

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Fatemeh Mohammadian

Street address

After Lashgar intersection, South Karegar street

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hosp_roozbeh@tums.ac.ir

Web page address

<http://roozbehhospital.tums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Poursina avenue; Keshavarz boulevard

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Niayesh Mohebbi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Clinical 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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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the study process, demographic information and patients' disease conditions, results of questionnaires and statistical analysis

When the data will become available and for how long

starting immediately after publication

To whom data/document is available

for researchers

Under which criteria data/document could be used

Use of documentation for other research and improvement of patients

From where data/document is obtainable

Refer to the related researcher (Arash Kalantar) at Email address below arash_kalantarmehrjardi@yahoo.com

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

Refer to the sites where the study was published, act via email and respond within one week after receiving the email.

Comments