Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Public title
Gingko 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 boxed 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Poursina avenue; Keshavarz boulevard
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1417613151
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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
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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
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