Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effectiveness of polyphenol rich extract of licorice as an adjunct therapy on improving symptoms of patients with Parkinson disease

Protocol summary

Study aim

Study of the effectiveness of polyphenol rich extract of licorice as an adjunct therapy on improving symptoms of patients with Parkinson disease

Design

In this phase III, randomized, controlled and double blind trial, 40 patients with Parkinson disease who are attending Emam Reza Clinic will be divided in two parallel groups (drug and placebo) based on block randomization. Diagnose of PD is done according to 2015 MDS criteria.

Settings and conduct

In this randomized controlled trial which is double blinded (participants, physician, neurology assistance in charge of data gathering and the statistician), 40 Parkinson diseases (PD) patients attending Emam Reza hospital will be randomly divided in two groups. Diagnosis of PD is done according to 2015 MDS criteria. Inclusion criteria are: Age between 30 to 80 years; idiopathic PD; initiation of PD symptoms in recent 6 years; The modified Hoehn and Yahr Scale: staging ≤ 3; no treatment changes within 4 weeks before starting the intervention. The exclusion criteria are: Warfarin, selective serotonin reuptake inhibitors (SSRI), Monoamine oxidase inhibitors (MAOIs), or diuretic consumption; History of diabetes, stroke; myocardial infarction; heart failure; renal failure; cardiac arrhythmia; liver diseases; uncontrolled hypertension and hypokalemia; pregnant and lactating women; complication of treatment including urticaria, pruritis, nasea and vomiting and vertigo Medications will be prepared with similar organoleptic properties under supervision of departments of Pharmacognosy and Pharmaceutics of Shiraz School of pharmacy. The syrups will be coded to be administered double blinded. Treatment group will receive polyphenol rich extract of licorice at the dose of 136 mg/ 5cc syrup, twice a day for 6 months. Placebo syrup will be administered at the same dose (5cc, twice a day for 6 months) to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Age between 30 to 80 years; idiopathic PD; initiation of PD symptoms in recent 6 years; The modified Hoehn and Yahr Scale: staging ≤ 3; no treatment changes within 4 weeks before starting the intervention. The exclusion criteria are: Warfarin; SSRI, MOA-I, or diuretic consumption; History of diabetes, stroke; myocardial infarction; heart failure; renal failure; cardiac arrhythmia; liver diseases; uncontrolled hypertension and hypokalemia; pregnant and lactating women; complication of treatment including urticaria, pruritis, nasea and vomiting and vertigo

Intervention groups

Intervention 1 Treatment group will receive polyphenol rich extract of licorice at the dose of 136 mg/ 5cc syrup, twice a day for 6 months, in adjunct to the routine treatment of Parkinson disease. Intervention 2 The control group will receive placebo syrup at the same dose (5cc, twice a day for 6 months) in adjunct to the routine treatment of Parkinson disease.

Main outcome variables

Unified Parkinson’s Disease Rating Scale (UPDRS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120305009204N3**
Registration date: **2018-03-12, 1396/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-12, 1396/12/21**
Update count: **0**

Registration date

2018-03-12, 1396/12/21

Registrant information

Name

Azadeh Hamedi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3242 4127

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of polyphenol rich extract of licorice as an adjunct therapy on improving symptoms of patients with Parkinson disease

Public title

Effect of polyphenol rich extract of licorice on improving symptoms of Parkinson disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30 to 80 years idiopathic parkinson disease (PD) initiation of PD symptoms in recent 6 years The modified Hoehn and Yahr Scale: staging ≤ 3 no treatment changes within 4 weeks before starting the intervention

Exclusion criteria:

Consumption of warfarin; selective serotonin reuptake inhibitors (SSRI), Monoamine oxidase inhibitors (MAOIs), or diuretic History of stroke; myocardial infarction; heart failure; renal failure or cardiac arrhythmia Uncontrolled hypertension and hypokalemia pregnant and lactating women Liver diseases Diabetes complication of treatment including urticaria, pruritis, nasea and vomiting and vertigo

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In this trial, participating patients, physicians, the neurological assistant in charge of interviewing patients and collecting data, care provider, as well as the statistician who analyze the data, will be blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical sciences, Zand Street, Shiraz Shiraz

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2016-02-07, 1394/11/18

Ethics committee reference number

IR.SUMS.MED.REC.1394.80

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
Unified Parkinson’s Disease Rating Scale (UPDRS)
Timepoint
First visit and every 6-8 weeks up to 6 months after intervention began
Method of measurement
Examination by the neurologist physician and Rating the diseases scale based on the Unified Parkinson's Disease Rating Scale (UPDRS)

Secondary outcomes

1

Description
Patients electrolytes level
Timepoint
At the beginning of the study and every 6-8 weeks for six months after the intervention began
Method of measurement
Serologic tests

2

Description
Patients blood pressure
Timepoint
At the beginning of the study and every 6-8 weeks for six months after the intervention began
Method of measurement
Measurement by the physician with a blood pressure monitor

Intervention groups

1

Description
Intervention group: Treatment group will receive polyphenol rich extract of licorice at the dose of 136 mg/ 5cc syrup, twice a day for 6 months, in adjunct to the routine treatment of Parkinson disease.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive placebo syrup at the same dose (5cc, twice a day for 6 months) in adjunct to the routine treatment of Parkinson disease
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Clinic Dependent to Shiraz University of Medical Science
Full name of responsible person
Dr. Peyman Petramfar; Dr. Azadeh Hamedi; Dr. Fatemeh Hajari
Street address
Emam Reza clinic, Namazi Square, Zand Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ali Poustfroushzadeh
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PO. Box 71345-1978, Central Building of Shiraz University of Medical Sciences, Zand Avenue. Shiraz, Iran Shiraz
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Phone
+98 71 3235 7882
Email
ali_po58@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Azadeh Hamedi; Dr.Peyman Petramfar

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacognosy

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Karafarin street, , School of Pharmacy, Shiraz, Iran

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Position
Associate Professor

Latest degree
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Other areas of specialty/work
Medical Pharmacy

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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
Potentially, all data, after unidentifing individuals, can be shared

When the data will become available and for how long
One year after publishing results

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Only path analysis for research purposes (Data will not be shared for business purposes or industries)

From where data/document is obtainable
Send an email to Dr. Azadeh Hamedi hamediaz@sums.ac.ir

What processes are involved for a request to access data/document
Send an email to Dr. Azadeh Hamedi, If applicable the documents will be sent

Comments