

# 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  $\leq 3$ ; 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, nausea 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  $\leq 3$ ; 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, nausea 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)

### Phone

+98 71 3242 4127

### Email address

hamediaz@sums.ac.ir

## 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  $\leq 3$  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

##### City

Shiraz

##### Province

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##### Postal code

71348714737

##### Phone

+98 71 3212 7000

##### Email

hamediaz@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Ali Poustfroushzadeh

##### Street address

PO. Box 71345-1978, Central Building of Shiraz University of Medical Sciences, Zand Avenue. Shiraz, Iran Shiraz

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##### Province

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71345-1978

##### 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 Hamed; Dr. Peyman Petramfar

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacognosy

**Street address**

Karafarin street, , School of Pharmacy, Shiraz, Iran

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7134814734

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Peyman Petramfar; Dr. Azadeh Hamed; Dr. Fatemeh Hajari

**Position**

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Medical Pharmacy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Azadeh Hamed

**Position**

Associate professor

**Latest degree**

Ph.D.

**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**

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 unidentifying 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 Hamed  
hamediaz@sums.ac.ir

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

Send an email to Dr. Azadeh Hamed, If applicable the documents will be sent

**Comments**