

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of herbal products Paeonia on the Treatment of children with refractory epilepsy

#### Protocol summary

##### Study aim

Effects of herbal products Favanya (Paeonia) on intractable epilepsy in children

##### Design

In a pilot-controlled clinical trial, 30 children with resistant epilepsy referring to the pediatric neurology clinic, who are eligible for inclusion criteria, are included in the study.

##### Settings and conduct

After referring the patients from the Pediatric Neurology Clinic of Ghaem Hospital, and signing the a written informed consent, patients will receive the Paeonia herbal product with the Common medicine drugs for one month.

##### Participants/Inclusion and exclusion criteria

Entry Criteria: Age range 1 year to 14 years,true drug resistant epilepsy, informed consent from parents  
Exclusion criteria: presence of chronic disease, history of false seizures, degenerative nerve disease

##### Intervention groups

Intervention group: paeonia recipient group

##### Main outcome variables

The number of seizures : Seizure severity

#### General information

##### Reason for update

##### Acronym

Paeonia RCT

##### IRCT registration information

IRCT registration number: **IRCT20131125015533N2**

Registration date: **2018-12-06, 1397/09/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-06, 1397/09/15**

Update count: **0**

##### Registration date

2018-12-06, 1397/09/15

#### Registrant information

##### Name

Mohammadreza Noras

##### Name of organization / entity

Faculty of Traditional Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3855 2189

##### Email address

norasmr901@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2018-12-06, 1397/09/15

##### Expected recruitment end date

2019-06-05, 1398/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The effect of herbal products Paeonia on the Treatment of children with refractory epilepsy

#### Public title

Favanya effect on intractable epilepsy in children

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

true drug-resistant epilepsy Age range 1 to 14 years

Conscious written consent from parents

##### Exclusion criteria:

Presence of degenerative nerve disease History of false seizures The presence of chronic disease

## Age

From **1 year** old to **14 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

University Street, Quraishi Building,

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944-91388

#### Approval date

2018-09-29, 1397/07/07

#### Ethics committee reference number

IR.Mums.REC.1397.159

## Health conditions studied

### 1

#### Description of health condition studied

Intractable epilepsy in children

#### ICD-10 code

G40

#### ICD-10 code description

Attack with loss of consciousness

## Primary outcomes

### 1

#### Description

Number of epileptic seizures; severity of epilepsy

#### Timepoint

At the beginning of the study, 7, 14, 21 and 28 days later

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

7, 14, 21 and 28 days after taking the drug

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Administration of paeonia officinalis hydroalcoholic extract as an oral solution of 20 mg / kg three times a day for four weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Children's Neurology Clinic of Ghaem Hospital in Mashhad

##### Full name of responsible person

Mehran Beiragi Tusi

##### Street address

Ahmadabad Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91766-99199

##### Phone

+98 51 3842 0818

##### Fax

+98 51 3845 3239

##### Email

Quaem.Medical.Center@mums.ac.ir

##### Web page address

<http://quaem.mums.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghghodi piadeh gheibi

**Street address**

Mashhad University of Medical Sciences, Mashhad  
University of Medical Sciences, Deputy of Research  
and Technology

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177899191

**Phone**

+98 51 3841 2081

**Fax**

+98 51 3843 0249

**Email**

vcresearch@mums.ac.ir

**Web page address**

<http://v-research.mums.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad zangoueipourfard

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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No.347 seyyed razi st. mashhad

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9177173415

**Phone**

+98 51 3606 1446

**Email**

zangoueipm941@mums.ac.ir

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammadreza Noras

**Position**

Educational deputy of the Faculty of Traditional  
Medicine and Mashhad Supplement

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Faculty of Iranian and Comprehensive Medicine,  
Mashhad, Azadi Square, Mashhad

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norasmr901@mums.ir

### Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Zangoueipourfard

**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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No.347 seyyedrazy 28

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177173415

**Phone**

+98 51 3606 1446

**Email**

## 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

All data will be released after unrecognizable individuals after the end of the study.

### When the data will become available and for how long

Start the access period 6 months after printing the results

### To whom data/document is available

Researchers at universities and institutes

### Under which criteria data/document could be used

In order to use the scientific results of the study in the treatment of patients, provided that the results of the study are significant.

### From where data/document is obtainable

Applicants will send their request to the email address zangoueipm941@mums.ac.ir.

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

After reviewing the application, the documentation will be sent within one month.

### Comments