Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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: paoenia 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
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Mohammadreza Noras
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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
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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

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vcresearch@mums.ac.ir

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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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Person responsible for scientific inquiries

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Ph.D.

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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
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