

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of therapeutic effects of herbal drug in the treatment of children with intractable epilepsy

Protocol summary

Summary

The aim of this study is to evaluate herbal drug on intractable seizures in children. This study is conducted in children neurologic department in an academic hospital. In a clinical trial, after ethical approval and obtaining written informed consent from children parents, 44 children who are referred to pediatrics neurology clinic with intractable seizures, are entered the study based on inclusion and exclusion criteria. Inclusion criteria are included age between 4 and 15 years, drug resistant epilepsy (DRE) and written informed consent from children parents. Exclusion criteria are included pseudoseizure, neurodegenerative disease, chronic diseases. There is no control group. Herbal drug is a capsule which contained *Paeoniae Radix*, *Anacyclus pyrethrum* and *Citrus aurantium L. var. amara*. Children are observed closely 3 months before herbal drug administration. They receive 250 mg single dose capsule for 13 weeks. Attacks frequency and duration are recorded. Complete blood cell count (CBC) and liver function tests (LFT) are performed for all children at the end of the third month and they are control for probable side effects and complication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091515790N2**

Registration date: **2016-10-10, 1395/07/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-10, 1395/07/19

Registrant information

Name

Mehrzad Mehrbani

Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for research affairs of Mashhad
University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of herbal drug in the
treatment of children with intractable epilepsy

Public title

Efficacy of herbal drug in the treatment of children with
intractable epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - Children aged between 4 and 15
years. - Drug resistant epilepsy (DRE) - Written informed
consent from children parents Exclusion criteria: -

Chronic diseases (such as diabetes mellitus, thyroid dysfunction, and heart, liver or kidney diseases) -
Pseudoseizure - Neurodegenerative disease

Age
From **4 years** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **44**

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

Daneshgah Ave.

City

Mashhad

Postal code

Approval date

2013-04-04, 1392/01/15

Ethics committee reference number

lr.mums.res.1392.911259161

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Primary outcomes

1

Description

frequency of seizure

Timepoint

At first and three months after intervention

Method of measurement

counting

2

Description

intensity of seizure

Timepoint

At first and three months after intervention

Method of measurement

Asking from parents

Secondary outcomes

1

Description

Drug reaction

Timepoint

At the end of the 3-month intervention period

Method of measurement

Questionnaire

Intervention groups

1

Description

Patients receive 250 mg single dose capsule (contained Anacyclus pyrethrum, Paeonia officinalis and Citrus aurantium varamara) for the three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric neurology clinic of Qaem hospital

Full name of responsible person

Seyedebrahim Mansoorinejad

Street address

Daneshgah Ave.

City

Mashad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for research affairs of Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Daneshgah street
City
Mashad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for research affairs of Mashhad
University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty