Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Curcumin on Reducing the Number of Seizures and Inflammatory Cytokines in Patients with Intractable Pediatric Epilepsy

Protocol summary

Study aim
Assessing the effect of curcumin on reducing the number of seizures and inflammatory cytokines in patients with intractable pediatric epilepsy

Design
This study was a double-blinded, randomized, crossover clinical trial. Simple purposive sampling was used to select 22 patients with intractable epilepsy.

Settings and conduct
The patients were randomly assigned to two groups to receive placebo and curcumin in turn. Patients were given 4 mg/kg of curcumin solution (Sinacurcumin®, each drop contains 4 mg nanocurcumin) or placebo for four weeks. At the end of each course and a two week wash-out interval, the drug and placebo were replaced. the parents and the researcher were unaware of the contents of the drug containers. If the duration or number of attacks increased, the drug would be discontinued immediately.

Participants/Inclusion and exclusion criteria
Patients who were diagnosed with intractable epilepsy and aged from three months to 16 years were included in the study. Patients with a history of pseudoseizures, status epilepticus, and other dangerous diseases or those with epilepsy secondary to another progressive neurodegenerative disorder were not included in the study.

Intervention groups
Patients received either a daily dose of 4 mg/kg curcumin or placebo as an add-on therapy for four weeks. After a two week washout period, the received treatment was replaced, and the new treatment was given for another four weeks.

Main outcome variables
the number of seizure attacks, inflammatory cytokine levels (IL1, IL2, IL4, IL6, IL8, IL10, MCP1, EGF, TNF, IFN gamma)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130811014330N7**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **retrospective**

Last update: **2019-12-26, 1398/10/05**
Update count: **0**

Registration date
2019-12-26, 1398/10/05

Registrant information

Name
Hamid Reza Rahimi

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-07-23, 1394/05/01

Expected recruitment end date
2015-08-23, 1394/06/01

Actual recruitment start date
2015-07-25, 1394/05/03

Actual recruitment end date
2015-08-27, 1394/06/05

Trial completion date
2015-10-25, 1394/08/03

Scientific title
The Effect of Curcumin on Reducing the Number of Seizures and Inflammatory Cytokines in Patients with Intractable Pediatric Epilepsy

Public title
Effect of Curcumin in Treatment of Pediatric Intractable Epilepsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Have at least 4 epileptic seizures in the last 4 weeks. Has been using anticonvulsant drugs for at least the last 1 month. The child's parents have informed consent. Not having a history of exacerbating seizures. Not having a cardiovascular, liver, or kidney disorder.

Exclusion criteria:
Diagnosing a curable cause for the epilepsy. Epilepsy is secondary to a progressive or neurodegenerative brain disorder. Having a history of status epilepsy within the past 3 months. Having multiple and uncountable seizures. Lack of cooperation in taking the medicines properly.

Age
From **3 months** old to **16 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **22**
Actual sample size reached: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly allocated to two groups by simple randomization based on computer-generated random numbers. Sealed drug containers were used in order to conceal the treatments to the clinician and patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
The clinician, parents, patients and the researchers were unaware of the contents of drug or placebo containers. Sealed drug containers were used in order to conceal the treatments to the clinician and patients.

Placebo
Used

Assignment
Crossover

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
Faculty of Medicine, University Campus, Azadi Square

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Mashhad

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Razavi Khorasan

Postal code
9138813944

Approval date
2015-05-09, 1394/02/19

Ethics committee reference number
IR.MUMS.REC.1394.42

Health conditions studied

1

Description of health condition studied
Pediatric intractable epilepsy

ICD-10 code
G40.919

ICD-10 code description
Epilepsy, unspecified, intractable, without status epilepticus

Primary outcomes

1

Description
number of seizure attacks

Timepoint
baseline (before starting intervention), 4, 6,10 weeks after intervention

Method of measurement
based on clinical report of attacks

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description
Intervention group 1: Patients were given 4 mg/kg curcumin solution daily for four weeks (Sinacurcumin®, each drop of solution contains 4 mg nanocurcumin). After a two-week washout period, the drug was replaced with the placebo, and the patient received 4 mg/kg placebo for another four weeks.

Category
Treatment - Drugs

2

Description
Intervention group 2: Patients were given 4 mg/kg placebo daily for four weeks. After a two-week washout period, the placebo was replaced with the drug, and the patient received 4 mg/kg curcumin solution (Sinacurcumin®, each drop of solution contains 4 mg nanocurcumin) for another four weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital Mashhad

Full name of responsible person
Dr. Farah Ashrafzadeh

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Sponsors / Funding sources

1

Sponsor

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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
Hamid Reza Rahimi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available