

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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)

Phone

+98 51 1800 2288

Email address

rahimhr891@mums.ac.ir

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

City

Mashhad

Province

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

Street address

Ghaem hospital, Ahmadabad Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0000

Email

Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Quraishi building of MUMS, Daneshgah St, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Phone

+98 51 3854 3031

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

Hamid Reza Rahimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Faculty of Medicine, Azadi Square, Pardis Campus, Mashhad-Iran,

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 1800 2288

Fax

+98 51 1800 2287

Email

rahimih891@mums.ac.ir

Person responsible for scientific 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

Street address

Faculty of Medicine, Azadi Square, Pardis Campus,
Mashhad-Iran,

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 1800 2288

Fax

+98 51 1800 2287

Email

rahimih891@mums.ac.ir

Faculty of Medicine, Azadi Square, Pardis Campus,
Mashhad-Iran,

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 1800 2288

Fax

+98 51 1800 2287

Email

rahimih891@mums.ac.ir

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

Person responsible for updating data**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

Street address