

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of thymoquinone in the treatment of infants with infantile refractory spasm

Protocol summary

Study aim

Comparison of the effect of thymoquinone in the treatment of infants with infantile refractory spasm

Design

The clinical trial had a control and intervention group, cross-over performed, no blinding and randomization was done, and the study was a phase 3 of clinical trial, which was performed on 20 patients.

Settings and conduct

This study was performed on 20 children with refractory infantile spasm referred to the Pediatric Neurology Clinic and hospitalized in the Pediatric Neurology Department of Mashhad Ghaem Hospital, cross over and they were divided into two groups of intervention and control who . Oral drops of thymoquinone Take for 3 weeks and the effect of this intervention on the number of seizures in the patient is examined weekly.

Participants/Inclusion and exclusion criteria

Infants who have seizures at least 3 times a week despite receiving at least 5 days of injectable corticotropin and at least one other drug to treat infantile spasm

Intervention groups

In the intervention group, the patient is given oral drops of thymoquinone for 3 weeks and in the control group, each patient is considered as his control in terms of personal characteristics, history of past diseases, number of seizures, family history and results of cell count and Bs, AST, ALT, BUN, Cr, is checked.

Main outcome variables

Number of seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200131046317N2**

Registration date: **2021-04-15, 1400/01/26**

Registration timing: **prospective**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

Registration date

2021-04-15, 1400/01/26

Registrant information

Name

Javad Akhondian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 7451

Email address

akhondianj@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of thymoquinone in the treatment of infants with infantile refractory spasm

Public title

The effect of thymoquinone on infantile spasm

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infants who, despite receiving at least 5 days of injectable corticotropin with at least one other appropriate drug for the treatment of infantile spasm, have at least 3 seizures per week as spasms or myoclonic Parental satisfaction

Exclusion criteria:

having liver or kidney disease. neurodegenerative disease.

Age

From **4 months** old to **18 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

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Razavi Khorasan

Postal code

9138813944

Approval date

2017-10-18, 1396/07/26

Ethics committee reference number

IR.MUMS.fm.REC.1395.549

Health conditions studied

1

Description of health condition studied

Infantile refractory spasm

ICD-10 code

G99.8

ICD-10 code description

Other specified disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

Seizures numbers

Timepoint

At the beginning of the study and weekly for 3 weeks while taking thymoquinone

Method of measurement

Based on parents' reports

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Because no two patients with drug-resistant infantile spasm (in terms of underlying causes of disease, inheritance of disease, socioeconomic status and parental care and types of drugs used) are not similar, so each patient is Considered as his control and will be monitored according to the test results for Bs, AST, ALT, BUN, Cr, and cell count (these include personal characteristics, history of past illnesses, number of seizures, family history, Patient information too).

Category

Treatment - Drugs

2

Description

Intervention group: Thymoquinone drops (consumed thymoquinone powder, produced by the German company Sigma, the drug form of which is an oral drop with an alcohol base, in each cc of which there is 10 mg of the active substance thymoquinone) as an additional drug for a period of 3 weeks is given to patients along with the initial medication. The researchers contact the patients by phone weekly and ask the parents about the number of seizures, the patient's general condition and possible complications at the end of each week and record it in the patient file. Then the results will be compared with the period before prescribing and finally statistical analysis will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Javad Akhondian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Javad Akhondian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

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