

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Registration timing: **prospective**

#### Study aim

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

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

Update count: **0**

#### 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.

#### Registration date

2021-04-15, 1400/01/26

#### 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.

#### 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

#### 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

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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.

#### 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

#### Main outcome variables

Number of seizures

#### Trial completion date

empty

#### General information

#### Scientific title

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

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200131046317N2**

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

#### 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

##### **Province**

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

**Street address**

Ghaem hospital, Ahmad Abad Ave

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**Email**

akhondianj@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**

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

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ramresearch@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**

Javad Akhondian

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Professor

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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