# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 controlwho . 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**
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**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

**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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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Mohsen Tafaghodi
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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
**Street address**
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## Person responsible for scientific inquiries

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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