# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 2026

## Effect of Magnesium on the Severity of Pain and Spasticity in Patients with Cerebral Palsy

## Protocol summary

**Study aim**
Evaluation of the effectiveness of magnesium prescription on the severity of pain and spasticity in patients with cerebral palsy

**Design**
Clinical trial without control group, single, not blinded, not randomized

**Settings and conduct**
31 patients with spastic cerebral palsy who referred to Shah-Vali and Shohada-e-Kargar hospitals of Yazd during 7 months were included. Patients received 100-300 mg of magnesium powder daily for 6 weeks.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 2 to 17 years old patients with spastic cerebral palsy Exclusion criteria: botox injection for at least 6 months, use of muscle relaxants and patients under 2 and over 17 years of age.

**Intervention groups**
Inclusion criteria: Patients with spastic cerebral palsy Exclusion criteria: Patients received 100-300 mg of magnesium powder daily for 6 weeks.

**Main outcome variables**
the severity of pain (FPS), Spasticity (MAS)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190817044550N1**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

**Registration date**
2020-02-01, 1398/11/12

**Registrant information**

**Name**
Mohammad Hoseini

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8950 2504

**Email address**
meditorha@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-01-21, 1397/11/01

**Expected recruitment end date**
2019-08-23, 1398/06/01

**Actual recruitment start date**
2019-01-21, 1397/11/01

**Actual recruitment end date**
2019-08-23, 1398/06/01

**Trial completion date**
2019-10-07, 1398/07/15

**Scientific title**
Effect of Magnesium on the Severity of Pain and Spasticity in Patients with Cerebral Palsy

**Public title**
Effect of Magnesium on Severity of Pain and Spasticity

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
patients with spastic cerebral palsy children in the age of 2 to 17 years old

**Exclusion criteria:**
Botox injection for at least 6 months The use of muscle relaxant drugs

**Age**

From **2 years** old to **17 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **31**
Actual sample size reached: **31**

**Randomization (investigator's opinion)**
N/A

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Islamic Azad University of Yazd

**Street address**
Shohada-e-Gomnam Blvd., Safaeih, Yazd

**City**
Yazd

**Province**
Yazd

**Postal code**
8916871967

**Approval date**
2019-06-25, 1398/04/04

**Ethics committee reference number**
IR.IAU.KHUISF.REC.1398.105

## Health conditions studied

### 1

**Description of health condition studied**
cerebral palsy

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Faces Pain Scale scores

**Timepoint**
6 months after patients entered to the study

**Method of measurement**
FPS test

### 2

**Description**
Modified Ashworth scale scores

**Timepoint**
6 months after patients entered to the study

**Method of measurement**
MAS test

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
The intervention group consisted of 30 eligible patients and the intervention was administered daily for 100–300 mg magnesium sulfate daily for 6 weeks, but given that our statistical population was children so we used magnesium powder.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Shah-Vali Hospital

**Full name of responsible person**
Ahmad Shajari

**Street address**
Shohada-e-Gomnam Blvd., Safayie, Yazd

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a_shajari@iauyazd.ac.ir

### 2

**Recruitment center**

**Name of recruitment center**
Shohada-e-Kargar Hospital

**Full name of responsible person**
Ahmad Shajari

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Modarres Blvd., Akramieh, Yazd

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Sponsor Vice-chancellor of research, Islamic Azad University, Faculty of Medicine, Branch of Yazd
**Full name of responsible person**
Ahmad Shajari
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Islamic Azad University
**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**
Islamic Azad University
**Full name of responsible person**
Ahmad Shajari
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
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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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not 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