

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**City**

Yazd

**Province**

Yazd

**Postal code**

8916871967

**Phone**

+98 35 3187 2200

**Email**

a\_shajari@iauyazd.ac.ir

**2****Recruitment center****Name of recruitment center**

Shohada-e-Kargar Hospital

**Full name of responsible person**

Ahmad Shajari

**Street address**

Modarres Blvd., Akramieh, Yazd

**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
۸۹۴۴۱۶۳۱۱۴  
**Phone**  
+98 35 3182 2000  
**Email**  
a\_shajari@iauyazd.ac.ir

## 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  
**Street address**  
Shohada-e-Gomnam Blvd., Safayie, YAzd  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916871967  
**Phone**  
+98 35 3187 2200  
**Email**  
a\_shajari@iauyazd.ac.ir  
**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  
**Street address**  
Shohada-e-Gomnam Blvd., Safahiye, Yazd  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916871967  
**Phone**  
+98 35 3187 2200  
**Email**  
a\_shajari@iauyazd.ac.ir

## Person responsible for scientific 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  
**Street address**  
Shohada-e-Gomnam Blvd., Safayie, Yazd  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916871967  
**Phone**  
+98 35 3187 2200  
**Email**  
a\_shajari@iauyazd.ac.ir

## Person responsible for updating data

#### 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  
**Street address**  
Shahada-e-Gomnam Blvd., Safayie, Yazd  
**City**  
Yazd  
**Province**  
Yazd

**Postal code**

8916871967

**Phone**

+98 35 3187 2200

**Email**

a\_shajari@iauyazd.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**

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