

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

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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

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Shohada-e-Gomnam Blvd., Safayie, Yazd

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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
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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 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