Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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