

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**Evaluating the effect of the comprehensive drug protocol for spasticity in cerebral palsy patients in terms of gait analysis, clinical examination, radiographic changes, complications and quality of life.**

### Protocol summary

#### Study aim

Determining the effectiveness of a comprehensive drug treatment protocol for spasticity in patients with cerebral palsy. Analysis of gait analysis, clinical examination, radiographic examination, drug side effects, quality of life.

#### Design

single arm group randomized trial, phase 2, group design of 31 patients

#### Settings and conduct

This study will be conducted in the orthopedic clinics of Tehran University of Medical Sciences on spastic cerebral palsy patients who have been included in the study according to the inclusion and exclusion criteria, based on a drug therapy protocol.

#### Participants/Inclusion and exclusion criteria

Patients with spastic cerebral palsy with or without a history of previous drug treatment and without a history of surgery within the past year.

#### Intervention groups

In this study, the effectiveness of drug therapy in cerebral palsy patients who were included in the study according to the inclusion and exclusion criteria will be examined according to the following protocol. Choice of treatment type: -Generalized spasticity treatment 1-First line: Baclofen (maximum dose 2.5mg/kg/day), Tizanidine (4mg/kg/day) 2-Second line: Dantrolene (12mg/kg/day), Diazepam (0.01-0.3mg/kg/day) 3-Third line (intraspinal baclofen (50 micrograms on the first day, 75 micrograms on the second day, 100 micrograms on the third day) - Treatment with local aim (both in generalized and local spasticity) 1-Botulinum toxin (upper, lower limbs): 30U/kg After giving the above drugs to each of the patients with the specified dosage in the first three visits, 3 and 6 months later, the patients are examined with examination and radiology and the results of the study are recorded

#### Main outcome variables

spasticity ;Range of motion;drug side effect

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20241215064059N1**

Registration date: **2025-01-04, 1403/10/15**

Registration timing: **prospective**

Last update: **2025-01-04, 1403/10/15**

Update count: **0**

#### Registration date

2025-01-04, 1403/10/15

#### Registrant information

##### Name

Mohammad Amin Choobdar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4424 4601

##### Email address

dr.amin.choobdar@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2025-01-17, 1403/10/28

#### Expected recruitment end date

2025-02-16, 1403/11/28

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluating the effect of the comprehensive drug protocol for spasticity in cerebral palsy patients in terms of gait analysis, clinical examination, radiographic changes, complications and quality of life.

**Public title**  
Investigating the effect of drug treatment protocol in cerebral

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with spastic cerebral palsy with or without a history of previous drug treatment without a history of surgery within the past year

**Exclusion criteria:**

Patients who have not returned for a follow-up visit during this period Patients who have had surgery within the past year

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2

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

**Sample size**  
Target sample size: 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 tehran University of Medical Sciences

**Street address**  
south Eskandari,Shokoufe ave

**City**  
Tehran

**Province**  
Tehran  
**Postal code**  
1319764853

**Approval date**  
2024-06-18, 1403/03/29

**Ethics committee reference number**  
IR.TUMS.IKHC.REC.1403.222

**Health conditions studied**

1

**Description of health condition studied**

spastic cerebral palsy

**ICD-10 code**

G80

**ICD-10 code description**

Cerebral palsy

**Primary outcomes**

1

**Description**

spasticity

**Timepoint**

The beginning of the study, 3 and 6 months later

**Method of measurement**

Ashworth scale

2

**Description**

range of motion

**Timepoint**

The beginning of the study, 3 and 6 months later

**Method of measurement**

Goniometer

3

**Description**

drug side effect

**Timepoint**

The beginning of the study, 3 and 6 months later

**Method of measurement**

Medication side effects questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

In this study, the effectiveness of drug therapy in cerebral palsy patients who were included in the study according to the inclusion and exclusion criteria will be examined according to the following protocol. Selection

of treatment type: - Treatment of generalized spasticity  
 1- First line: Baclofen (maximum dose 2.5 mg/kg/day), Tizanidine (4 mg/kg/day)  
 2- Second line: Dantrolene (12 mg/kg/day), Diazepam (0.01-0.3 mg/kg/day)  
 3- Third line (intraspinal baclofen (50 micrograms on the first day, 75 micrograms on the second day, 100 micrograms on the third day) - Treatment with local aim (both in generalized and local spasticity)  
 1- Botulinum toxin {Dysport, Masport, Dyston} (upper, lower limbs): 30 U/kg  
 Treatment based on specific conditions - Pain (botulinum toxin, Tizanidine, oral baclofen, Diazepam, Dantrolene, intraspinal baclofen) - Disorder Sleep (tizanidine, oral baclofen, diazepam) - mixed type with dystonia (botulinum toxin, oral baclofen, diazepam) - post-operative pain due to spasm (diazepam, botulinum toxin, oral baclofen) - seizures (tizanidine, diazepam \* Caution regarding the use of baclofen, dantrolene and intrathecal baclofen; After giving the above drugs to each of the patients with the specified dosage in the first three visits, 3 and 6 months later, the patients are examined with examination and radiology and the results of the study are recorded. If the drug results improve, it is continued, and if the results are not favorable, the second line is started.

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Theran Imam khomeini hospital complex

###### Full name of responsible person

Mohamad Amin Choobdar Omrani

###### Street address

Keshavarz blv

###### City

Tehran

###### Province

Tehran

###### Postal code

۱۴۱۹۷۳۳۱۴۱

###### Phone

+98 21 6119 2613

###### Email

Imamhospital@tums.ac.ir

#### 2

##### Recruitment center

###### Name of recruitment center

Shariati hospital

###### Full name of responsible person

Mohamad Amin Choobdar Omrani

###### Street address

north kargar ave

###### City

Tehran

###### Province

Tehran

###### Postal code

1411713135

###### Phone

+98 21 8490 1000

###### Email

shariatihosp@tums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tehran University of Medical Sciences

###### Full name of responsible person

Sina Rezaei

###### Street address

poorsina ave

###### City

Tehran

###### Province

Tehran

###### Postal code

1461884513

###### Phone

+98 21 8163 3619

###### Fax

###### Email

aminch2009@gmail.com

###### Web page address

###### Grant name

###### Grant code / Reference number

###### Is the source of funding the same sponsor organization/entity?

Yes

###### Title of funding source

Tehran 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

Tehran University of Medical Sciences

###### Full name of responsible person

Mohammad Amin Choobdar

###### Position

Resident

###### Latest degree

Medical doctor

###### Other areas of specialty/work

Orthopedics

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dr.amin.choobdar@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Orthopedics

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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**Province**

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**Postal code**

1319764853

**Phone**

+98 11 4424 4601

**Fax****Email**

dr.amin.choobdar@gmail.com

**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared

**When the data will become available and for how long**

The access period begins immediately after the results are published.

**To whom data/document is available**

All researchers in the field of medical and pharmaceutical sciences

**Under which criteria data/document could be used**

Researchers in the fields of medical and pharmaceutical sciences have permission to access the data. There are no restrictions on data analysis.

**From where data/document is obtainable**

mohammad amin choobdar 09200567515

dr.amin.choobdar@gmail.com

**What processes are involved for a request to access data/document**

پس از تماس و اعلام درخواست ابتدا مدارک مربوط به فرد درخواست دهنده جهت تایید ارسال شده و طی یک هفته داده ها از طریق ایمیل تحویل خواهد شد

**Comments**