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)
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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
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۱۴۱۹۷۳۳۱۴۱
Phone
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Email
Imamhospital@tums.ac.ir

2

Recruitment center

Name of recruitment center
Shariati hospital
Full name of responsible person
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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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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