

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study the Effects of Cerebrolysin on the Improvement of Spasticity and Behavioral Development of Patients with Cerebral Palsy

Protocol summary

Summary

Objectives: Studying the Effects of Cerebrolysin on the Improvement of Spasticity and Behavioral Development of Patients with Cerebral Palsy. Design: Non-randomized, non_blinded, single-center. Study population: Participants of study include 6 to 12 years old patients with cerebral palsy. Major inclusion criteria: 1. Patients 6 to 12 years old 2. Participants with cerebral palsy without persistent seizure attacks. Major exclusion criteria: 1. The co-morbidity of cerebral palsy with persistent seizure attacks. 2. Presence of renal failure in participants. Intervention: Administration of 0.1 cc/Kg dose of Cerebrolysin IM injection to participants, 5 times a week for one month. Participants would give one month break without injection. For the third month, Cerebrolysin would be administered to the participants at the 0.1 cc/Kg dose as IM injection at the following orders: four times per week in the first week, three times per week in the second week, two times per week in the third week and once a week for the fourth week. The injection would be continued once a week for six months if the improvement in spasticity being observed followed the fourth week of the second course of treatment. Main outcome measures: The main purpose of study is to assess the improvement of spasticity in patients with cerebral palsy by using the Asworth's Modified Scale (AMS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107226907N3**
Registration date: **2015-12-02, 1394/09/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6612 9252

Email address

ashrafim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Effects of Cerebrolysin on the Improvement of Spasticity and Behavioral Development of Patients with Cerebral Palsy

Public title

The effect of Cerebrolysin in cerebral palsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria includes: 1. Participants must be 6 to 12

years old. 2. Participants must be free of grand mal seizure attacks. Exclusion criteria includes: 1. Participants with diagnosis of cerebral palsy and grand mal seizure attacks co-morbidity have been excluded of the study. 2. Participants with renal failure disorder would not be participated in the study.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **26**

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

Research department, Tehran University of Medical Sciences' headquarters, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2015-04-08, 1394/01/19

Ethics committee reference number

142077-9111165027

Health conditions studied

1

Description of health condition studied

Cerebral Palsy

ICD-10 code

G80

ICD-10 code description

Excl: hereditary spastic paraplegia

2

Description of health condition studied

Spastic diplegic cerebral palsy

ICD-10 code

G80

ICD-10 code description

Congenital spastic paralysis (cerebral) Spastic cerebral palsy NOS

3

Description of health condition studied

Spastic quadriplegic cerebral palsy

ICD-10 code

G80.0

ICD-10 code description

Spastic tetraplegic cerebral palsy

4

Description of health condition studied

Spastic hemiplegic cerebral palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

5

Description of health condition studied

Dyskinetic cerebral palsy

ICD-10 code

G80.3

ICD-10 code description

Athetoid cerebral palsy Dystonic cerebral palsy

6

Description of health condition studied

Ataxic cerebral palsy

ICD-10 code

G80.4

ICD-10 code description

Ataxic cerebral palsy

7

Description of health condition studied

Other cerebral palsy

ICD-10 code

G80.8

ICD-10 code description

Mixed cerebral palsy syndromes

8

Description of health condition studied

Cerebral palsy, unspecified

ICD-10 code

G80.9

ICD-10 code description

Cerebral palsy NOS

9

Description of health condition studied

Spastic diplegic cerebral palsy

ICD-10 code

G80.1

ICD-10 code description

Congenital spastic paralysis (cerebral) Spastic cerebral palsy NOS

Primary outcomes

1

Description

Degree of improvement in spasticity

Timepoint

Before intervention, At the end of the first month of treatment course, At the end of third month of second course of intervention

Method of measurement

Asworth Scoring

Secondary outcomes

empty

Intervention groups

1

Description

Administration of 0.1 cc/Kg dose of Cerebrolysin IM injection to participants, 5 times a week for one month. Participants would give one month break without injection. For the third month, Cerebrolysin would be administered to the participants at the 0.1 cc/Kg dose as IM injection at the following orders: four times per week in the first week, three times per week in the second week, two times per week in the third week and once a week for the fourth week. The injection would be continued once a week for six months if the improvement in spasticity being observed followed the fourth week of the second course of treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Children's Medical Center

Full name of responsible person

Dr. Elnaz Fattah Dizaji

Street address

Children's Medical center, 62 QaribSt.,
KeshavarzBlvd., Tehran 14194, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran university of medical sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Research department, Tehran university of medical sciences' head quarters, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Tehran university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Children's Medical Center

Full name of responsible person

Elnaz Fattah Dizaji

Position

Pediatrics Resident

Other areas of specialty/work

Street address

Children's Medical Center, Dr. Mohammad Gharib street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Children's Medical Center

Full name of responsible person

Elnaz Fattah Dizaji

Position

Pediatrics Resident

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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

Children's medical center

Full name of responsible person

Elnaz Fattah Dizaji

Position

Pediatrics Resident