Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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 spapsticity
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 Reseach, 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 Reseach, 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
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Person responsible for scientific inquiries

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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