

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The evaluation of Cerebrolysin effect on cognitive and verbal aspects of children suffering from autism spectrum disorder

#### Protocol summary

##### Summary

Objective : Determination of Cerebrolysin effects on cognitive and verbal aspects of children suffering from autism spectrum disorder Design: Thirty six children ranging in age from 3 to 10 year-old children suffering from Autism spectrum disorder referred to pediatric neurologic clinic in pediatric center of excellence from August 2014 to February 2015 are included in this study. No blinding and randomization were done. Setting and Conduct: Childhood Autistic Rating Scale (CARS) questionnaire includes 15 sections. It evaluates cognitive and verbal aspects of Autistic children. Patients receive a grade from 1 to 4 in each of 15 sections. Patients are evaluated again by CARS questionnaire one month after completing the treatment. At the end, according to changes in grades in second evaluation, the efficacy of medication will be evaluated in four aspects of so called questionnaire. Participants including major eligible criteria: selected children are required not to receive any kinds of new medications during the recent three months ago and having neither past history of seizure nor intracerebral hemorrhage. Intervention: Cerebrolysin is prescribed by a supervisor, injected intramuscularly, 1cc in 3 days a week in first month of study, followed by gradual decrease in dose during the second month ( two injections in first week, two injection in second week, one injection in third week and, finally one injection in forth week). Main outcome measures: -verbal and non-verbal communication, emotional response, relationship to people

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100424337N1**

Registration date: **2015-12-23, 1394/10/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-23, 1394/10/02

##### Registrant information

###### Name

mohammad vafaeeshahi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2267 9834

###### Email address

m-vafaeeshahi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2014-08-23, 1393/06/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of Cerebrolysin effect on cognitive and verbal aspects of children suffering from autism spectrum disorder

##### Public title

Cerebrolysin effect On cognitive and verbal aspects of children suffering from autism spectrum disorder

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: All 3 to 10 year-old children suffering from Autism spectrum disorder referred to pediatric neurologic clinic in pediatric center of excellence from August 2014 to February 2015 are included in this study.

Exclusion criteria: receive of any kinds of new medications during the recent three months ago; past history of uncontrolled seizure; past history of intra-cerebral hemorrhage.

## Age

From **3 years** old to **10 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Not randomized

## 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 Science

##### Street address

Ghods Street, Keshavarz Boulevard

##### City

Tehran

##### Postal code

#### Approval date

2015-06-24, 1394/04/03

#### Ethics committee reference number

IR.TUMS.REC.1394.257

## Health conditions studied

### 1

#### Description of health condition studied

Autism spectrum disorders

## ICD-10 code

F84.0

## ICD-10 code description

## Primary outcomes

### 1

#### Description

Verbal and Non-verbal Communication, Emotional response, relationship to people

#### Timepoint

Three Months

#### Method of measurement

Childhood Autism Rating Scale Test

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

Intramuscular Cerebrolysin injection 1cc in 3 days a week in first month of study, followed by gradual decrease in dose during the second month ( two injections in first week, two injection in second week, one injection in third week and, finally one injection in forth week). cerebrolysin is a low molecular neuropeptide and free amino acid that has neurotrophic effects. It is produced in GMP factory ( Australia)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Children Medical Center

##### Full name of responsible person

Mohammad Vafae-Shahi

##### Street address

##### 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**

Masoud yunesian

**Street address**

Tehran University of medical science

**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****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*

**2****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

mohammad vafae-shahi

**Street address**

children medical center

**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****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**

Tehran University of Medical Science

**Full name of responsible person**

Mohammad Vafae-Shahi

**Position**

fellow of Pediatric Neurology

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

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*