

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Efficacy and Safety of Augmenting Autologous Bone Marrow Stem Cell Therapy in Routine Treatment of Children with Autism Spectrum Disorder: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

To determine the efficacy and safety of treatment with autologous bone marrow stem cells compared with the routine treatment of children with ASD

##### Design

The present parallel, single-blind, and randomized clinical trial was conducted on the ASD children referred to the Pediatric Clinic at Ibn-e-Sina Hospital and Establishments covered by the Social Welfare Organization, including the Charity and Rehabilitation Centers and Exceptional Education Centers in Mashhad, Iran

##### Settings and conduct

The present parallel, single-blind, and randomized clinical trial was conducted on the ASD children referred to the Pediatric Clinic at Ibn-e-Sina Hospital and Establishments covered by the Social Welfare Organization, including the Charity and Rehabilitation Centers and Exceptional Education Centers in Mashhad, Iran

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: the age range of  $\geq 5$  and  $\leq 15$  years and diagnosis of ASD. A long history of allergic reactions, seizures during the past six months, brain trauma, moderate to severe extrapyramidal symptoms and tardive dyskinesia, severe self-injury behavior, autoimmune diseases, severe hematologic and pulmonary disease (such as pneumonia, asthma, malignancy and immune deficiency), severe focal or systemic infection (such as AIDS, hepatitis and syphilis), kidney and liver problems, anemia and hemoglobin level less than 8 g/dL, bone marrow- associated diseases.

##### Intervention groups

This parallel, single-blind, and randomized clinical trial was conducted on ASD children aged 5-15 years old . The patients were randomly assigned to one of the case group (intervention with MSC plus rehabilitation therapy)

or the control group (rehabilitation therapy alone).

##### Main outcome variables

of CARS total score, GARS-II, Autism Index, Global improvement, and CGI-S

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201512315280N22**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **retrospective**

Last update: **2018-09-28, 1397/07/06**

Update count: **1**

##### Registration date

2016-05-28, 1395/03/08

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2015-04-04, 1394/01/15  
**Expected recruitment end date**

2015-08-23, 1394/06/01  
**Actual recruitment start date**

2015-04-21, 1394/02/01  
**Actual recruitment end date**

2015-08-30, 1394/06/08  
**Trial completion date**

### Scientific title

Efficacy and Safety of Augmenting Autologous Bone Marrow Stem Cell Therapy in Routine Treatment of Children with Autism Spectrum Disorder: A Randomized Clinical Trial

### Public title

Efficacy Stem Cell in Treatment Autism

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

age range of  $\geq 5$  and  $\leq 15$  years a definite diagnosis of ASD based on DSM

#### Exclusion criteria:

a long history of allergic reactions seizures during the past six months brain trauma moderate to severe extrapyramidal symptoms and tardive dyskinesia severe self-injury behavior autoimmune diseases severe hematologic and pulmonary disease (such as pneumonia, asthma, malignancy and immune deficiency) severe focal or systemic infection (such as AIDS, hepatitis and syphilis) kidney and liver problems anemia and hemoglobin level less than 8 g/dL bone marrow-associated diseases receiving other treatments affecting the health of stem cell therapy

### Age

From **5 years** old to **15 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Care provider

### Sample size

Target sample size: **36**

Actual sample size reached: **32**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The random allocation of patients was done using the numbered, sealed and stapled envelopes. To hide the allocation, random numbers were created using the <https://www.random.org/> site and placed by one of the colleagues outside the research team inside the paper envelopes. After explaining the study objectives to the parents of the eligible patients, an envelope was taken for the individual and then, based on the envelope contents, the person was enrolled in the case group receiving SCs and the rehabilitation treatment or in the control group receiving rehabilitation therapy alone

### Blinding (investigator's opinion)

Single blinded

### Blinding description

This single-blind trial was conducted in such a way that only the psychologist assessing the status of children was unaware of interventions.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical sciences

##### Street address

Administration Center(Qoreishi Building), Daneshgah St., Mashhad, Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

345 - 91357

#### Approval date

2015-02-18, 1393/11/29

#### Ethics committee reference number

930960

## Health conditions studied

### 1

#### Description of health condition studied

Autism

#### ICD-10 code

F84.0

#### ICD-10 code description

Childhood autism

## Primary outcomes

### 1

#### Description

Autism

#### Timepoint

Baseline, 1, 3, 12 months

#### Method of measurement

GARSII test

## 2

### Description

Autism

### Timepoint

Baseline, 1, 3, 12 months

### Method of measurement

CARS test

## 3

### Description

Illness severity

### Timepoint

Baseline, 1, 3, 12 months

### Method of measurement

Clinical Global Impression (CGI)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In intervention group stem cell intratecal transplantation is doing augmentation of usual treatment.

#### Category

Treatment - Surgery

### 2

#### Description

In control group Patients get routine treatment .

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ibn e Sina Hospital

##### Full name of responsible person

Dr Narges Sharifzadeh

##### Street address

Ibn-e-Sina Hospita, Bu-Ali Sq., Amel Blvd., Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

345 - 91357

##### Phone

+98 51 3841 3007

##### Email

FayyaziMR@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mahyar Mirheydari

##### Street address

Administration Center(Qoreishi Building), Daneshgah St., Mashhad, Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

345 - 91357

##### Phone

+98 51 3841 3007

##### Email

FayyaziMR@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Narges Sharifzadeh

##### Position

Psychiatrist

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd., Mashhad,Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

345 - 91357

**Phone**

+98 51 3711 2701

**Fax**

**Email**

narges.sharifzadeh@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohammad reza Fayyazi bordbar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,  
Mashhad,Iran.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

345 - 91357

**Phone**

+98 51 3711 2540

**Fax**

**Email**

narges.sharifzadeh@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Narges Sharifzadeh

**Position**

psychiatrist

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,  
Mashhad,Iran.

**City**

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**Postal code**

345 - 91357

**Phone**

+98 51 3711 2540

**Fax**

**Email**

narges.sharifzadeh@gmail.com

**Web page address**

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable