Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥5 and ≤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 Scinces, 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

2016-08-29, 1395/06/08

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 ≥5 and ≤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 intratechal 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
psychiattrist
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 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