# Allogeneic Umbilical Cord Mesenchymal Stem Cell Therapy for Autism

**This study is currently recruiting participants.** (see Contacts and Locations)

*Verified July 2014* by Translational Biosciences

**Sponsor:**
Translational Biosciences

**Information provided by (Responsible Party):**
Translational Biosciences

**ClinicalTrials.gov Identifier:**
NCT02192749

First received: July 12, 2014
Last updated: July 15, 2014
Last verified: July 2014
History of Changes



## Purpose

**Allogeneic** (not from the subject) human **umbilical cord** tissue-derived **stem cells** administered intravenously (IV) in a series of 4 infusions every 3 months over the course of one year is safe and will induce a therapeutic effect in **autism** patients.

| Condition | Intervention | Phase |
|---|---|---|
| **Autism** | Biological: **Umbilical cord mesenchymal stem cells** | Phase 1<br>Phase 2 |

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Open, Prospective Trial of **Treatment** of **Autism** Spectrum Disorders (ASD) Using Intravenous Infusion of **Umbilical Cord** Tissue **Mesenchymal Stem Cells** (UC-MSC)

**Resource links provided by NLM:**

MedlinePlus related topics: Autism

U.S. FDA Resources

**Further study details as provided by Translational Biosciences:**

Primary Outcome Measures:

- Number of participants with adverse events [ Time Frame: 89 weeks ] [ Designated as safety issue: Yes ]

Secondary Outcome Measures:

- Number of participants with a change in disability as measured by the **Autism Treatment** Evaluation Checklist (ATEC) [ Time Frame: 13 weeks, 25 weeks, 37 weeks, 49 weeks, 89 weeks ] [ Designated as safety issue: No ]
- Number of participants with a change in disability as measured by the Childhood **Autism** Rating Scale (CARS) [ Time Frame: 13 weeks, 25 weeks, 37 weeks, 49 weeks, 89 weeks ] [ Designated as safety issue: No ]
- Change from baseline macrophage-derived chemokine (MDC) [ Time Frame: 13 weeks, 25 weeks, 37 weeks, 49 weeks, 89 weeks ] [ Designated as safety issue: No ]
- Change from baseline thymus and activation-regulated chemokine (TARC) [ Time Frame: 13 weeks, 25 weeks, 37 weeks, 49 weeks, 89 weeks ] [ Designated as safety issue: No ]

| | |
|---|---|
| Estimated Enrollment: | 20 |
| Study Start Date: | July 2014 |
| Estimated Study Completion Date: | August 2017 |
| Estimated Primary Completion Date: | August 2016 (Final data collection date for primary outcome measure) |

| Arms | Assigned Interventions |
|---|---|
| Experimental: **Umbilical cord mesenchymal stem cells** | Biological: **Umbilical cord mesenchymal stem cells** |

## Eligibility

| | |
|---|---|
| Ages Eligible for Study: | 6 Years to 16 Years |
| Genders Eligible for Study: | Both |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Male or Female
- Ages 6 to 16
- Diagnostic and Statistical Manual of Mental Disorders (DSM IV) diagnosis of autism confirmed by Autism Diagnostic Observation Schedule (ADOS) and/or Autism Diagnostic Interview-Revised (ADI-R)
- No anticipated changes in treatment for the study duration (e.g., diet, nutrients)
- No additional biomedical treatments started 6 weeks prior to enrollment
- No changes in dietary management for 3 months prior to enrollment
- Ambulatory or require minimum support walking, per parent
- Able to sit still for 5 minutes or longer with a preferred toy item, per parent
- Adequate vision and hearing for the purposes of test administration, per parent
- Adequate arm-hand-finger coordination (i.e., able to point) for learning and cognitive tasks used in outcome measurement, per parent
- Stable and controlled mental disorder
- Under the care of a caregiver willing to participate by attending regularly scheduled appointments and completing the necessary measures
- Normal heavy metals test for lead and mercury levels performed within 30 days of first stem cell infusion
- Must provide name and specialty of specialist who has made Autism Spectrum Disorder (ASD) diagnosis
- Adequate financial means to cover $7,200 (US Dollars) plus travel expenses

Exclusion Criteria:

- Significant prematurity at birth (less than 32 weeks gestation); or birth weight significantly below normal for gestational age (SGA - small for gestational age)
- mental retardation
- seizure disorder
- auto-immune conditions
- history of head trauma and other neurological or medical conditions
- Abnormal heavy metals test for lead and mercury performed within 30 days of first stem cell infusion
- Prior stem cell therapy of any kind

## Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02192749

**Locations**

**Panama**

**Stem Cell** Institute — **Recruiting**
Panama City, Panama
Contact: Marggie Arosemena +507 306-2633 trials@translationalbiosciences.com
Principal Investigator: Jorge Paz-Rogriguez, MD

**Sponsors and Collaborators**

Translational Biosciences

**Investigators**

Principal Investigator: Nelson Novarro, MD

Principal Investigator: Jorge Paz-Rodriguez, MD Translational Biosciences / **Stem Cell** Institute Panama

## More Information

No publications provided

| | |
|---|---|
| Responsible Party: | Translational Biosciences |
| ClinicalTrials.gov Identifier: | NCT02192749 History of Changes |
| Other Study ID Numbers: | TBS-UCMSC-ASD001 |
| Study First Received: | July 12, 2014 |
| Last Updated: | July 15, 2014 |
| Health Authority: | Panama: Ministry of Health |

Keywords provided by Translational Biosciences:
**autism**
**umbilical cord**
**mesenchymal**
**stem cells**

Additional relevant MeSH terms:
**Autistic** Disorder
Child Development Disorders, Pervasive
Mental Disorders Diagnosed in Childhood
Mental Disorders

ClinicalTrials.gov processed this record on July 16, 2014

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