

Allogeneic Umbilical Cord Mesenchymal Stem Cell Therapy for Autism

This study is ongoing, but not recruiting participants.

Sponsor:	Translational Biosciences
Collaborators:	
Information provided by (Responsible Party):	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT02192749

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/Vaccine: Umbilical cord mesenchymal stem cells	Phase 1/ Phase 2

Study Type: Interventional

Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study

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

Further study details as provided by Translational Biosciences:

Primary Outcome Measure:

- 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 Primary Completion Date: August 2016

Estimated Study Completion Date: August 2017

Arms	Assigned Interventions
Experimental: Umbilical cord mesenchymal stem cells	Biological/Vaccine: 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

Locations

Panama

Stem Cell Institute

Panama City, Panama

Investigators

Principal Investigator: Nelson Novarro, MD

Principal Investigator: Jorge Paz-Rodriguez, MD

Unaffiliated

Translational Biosciences /
Stem Cell Institute Panama

More Information

Responsible Party: Translational Biosciences

Study ID Numbers: TBS-UCMSC-ASD001

Health Authority: Panama: Ministry of Health

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