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Trial record **1 of 3** for: umbilical cord blood for autism
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Autologous Cord Blood Stem Cells for Autism

This study is currently recruiting participants.

Verified August 2012 by Sutter Health

Sponsor:
Sutter Health

Information provided by (Responsible Party):
Michael Chez, MD, Sutter Health

ClinicalTrials.gov Identifier:
NCT01638819

First received: June 26, 2012
Last updated: August 20, 2012
Last verified: August 2012
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	June 26, 2012
Last Updated Date	August 20, 2012
Start Date ICMJE	August 2012
Estimated Primary Completion Date	August 2013 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: July 9, 2012)**	Change in language [Time Frame: Baseline and 6 months] [Designated as safety issue: No] Change in language as measured by the Receptive One-Word Vocabulary Test (ROWVT) and Expressive One-Word Vocabulary Test (EOWVT) at baseline and six months following infusion of stem cells from AUCB or infusion of placebo.
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT01638819 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: July 9, 2012)**	• Improved Behavior/Learning [Time Frame: Baseline and 6 months] [Designated as safety issue: No] Change in the Vineland Adaptive Behavior Scales between baseline and six months after infusion of AUCB containing stem cells • Improved Behavior [Time Frame: Baseline and 6 months] [Designated as safety issue: No] Change in Pervasive Developmental Disorders Behavior Index (PDDBI) between baseline and six months after infusion of AUCB containing stem cells • Change in Serum Values [Time Frame: Baseline and 6 months] [Designated as safety issue: No] Change in the following between baseline and six months after infusion of AUCB containing stem cells as measured by: • Serum (TNF) alpha, Interleukin 1-alpha (IL-1α), interleukin 13(IL-13), Interleukin -1β, Interleukins 6, 10, 13
Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome	*Not Provided*

Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Autologous **Cord Blood** Stem Cells for **Autism**
Official Title ICMJE	A Randomized, Blinded, Placebo-controlled, Crossover Study to Assess the Efficacy of Stem Cells From Autologous **Umbilical Cord Blood** to Improve Language and Behavior in Children With **Autism**
Brief Summary	Evaluate the efficacy of one infusion of stem cells from autologous **umbilical cord blood** in patients with **autism** over six months after infusion as measured by changes in expressive and receptive language. Also demonstrate improved behavior, learning, and changes in Serum tumor necrosis factor alpha (TNF-α), tumor necrosis factor beta (TNF-β), interleukin 1-alpha (IL-1α), interleukin 1-beta (IL-1β), interleukin 6 (IL-6), interleukin 10 (IL-10), and interleukin 13 (IL-13).
Detailed Description	This is a single-center, randomized, placebo-controlled, crossover outpatient study with 15 subjects receiving one infusion of autologous umbilical cord blood (AUCB) containing a minimum of 10 million total nucleated cells per kilogram (TNC/kg) and 15 subjects receiving an infusion of placebo (saline). After the 24-week follow-up testing is conducted, the groups will crossover so that patients who initially received AUCB will receive placebo and patients who received placebo at baseline will receive the cord blood. Both groups will be tested again 24-weeks after infusion. The neuropsychologist, PI, staff from Cord Blood Registry (CBR), and parents will be blinded as to the infusion sequence. The duration of participation for each study subject is approximately 55 weeks. This includes one screening visit over a period of approximately 6 weeks, one visit for baseline testing, one day for infusion of TNC (minimum 10 million/kg) or saline placebo followed by 24 weeks of follow-up. A second baseline visit is conducted at week-24 with the second infusion of TNC or saline placebo occurring 5-7 days after. Twenty-four additional weeks of follow-up occur after the second infusion.
Study Type ICMJE	Interventional
Study Phase	Phase 2
Study Design ICMJE	Allocation: Randomized Endpoint Classification: Efficacy Study Intervention Model: Crossover Assignment Masking: Double Blind (Subject, Caregiver, Investigator) Primary Purpose: Treatment
Condition ICMJE	**Autism**
Intervention ICMJE	• Biological: Autologous **Cord Blood** Stem Cells One infusion of 60 ml syringe of study product • Biological: Placebo Saline
Study Arm (s)	• Experimental: Autologous **Cord Blood** Stem Cells Intervention: Biological: Autologous **Cord Blood** Stem Cells • Placebo Comparator: Placebo Saline Intervention: Biological: Placebo
Publications *	Mauron A. [In Process Citation]. Rev Med Suisse. 2012 Sep 19;8(354):1795. French.

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Recruiting
Estimated Enrollment ICMJE	30
Estimated Completion Date	August 2013
Estimated Primary Completion Date	August 2013 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: • Age 2 to 7 years of age • Diagnosis of Autistic Disorder as diagnosed by the DSM-IV-TR developmental delays, and ADOS • A sufficient quantity of autologous cord blood stored at Cord Blood Registry that was stored and processed using the Thermogenesis AutoXpress Platform • Stable on any current medications for at least 2 months prior to infusion of cord blood • Medical records indicating that patient does not have genetic conditions such as cerebral palsy, cystic fibrosis, muscular dystrophy, crohns disease, rheumatoid disease, fragile X, Retts Syndrome, Angelman Syndrome, tuberous sclerosis, epilepsy, or known genetic defects that overlap autism spectrum. • Results of an EEG within 12-months of baseline • English speaking Exclusion Criteria: • CNS infection • Extreme prematurity (< 34 weeks gestation) • Severe Cognitive Disability IQ below 45 with autism • Clinical seizure activity within 6 months of baseline • Lennox Gastaut syndrome or infantile spasms • Dravet syndrome • HIV, renal or hepatic impairment • Prior hematological or malignant disease • Fever of 101 F within 2 weeks prior to infusion • Serious CNS infection or trauma • Unwilling to commit to follow-up • Mental illness including schizophrenia • Pervasive Developmental Disorder—Not Otherwise Specified • Asperger's Disorder • Cord blood unit is less than 85% viable, has a TNC of less than 10 million/kg, CD34+ count of less than 0.3% or sterility testing results are positive • Garlic allergy • Previous adverse reaction to Dimethyl Sulfoxide (DMSO) • Maternal medical records indicate communicable diseases including HIV, Hepatitis B or C, syphilis, cytomegalovirus (CMV) • Currently taking anti-inflammatory medications • History of asthma who may potentially require treatment with steroids • Inflammatory Disease • Renal/hepatic disease: serum Creatinine > 1.5 mg/dl and total Bilirubin > 1.5 mg/dl • Allergic to diphenhydramine (Benadryl)
Gender	Both
Ages	2 Years to 7 Years
Accepts Healthy Volunteers	No

Contacts ICMJE	Contact: Heather Harris, MS | 1-888-536-9826
Location Countries ICMJE	United States

Administrative Information

NCT Number ICMJE	NCT01638819
Other Study ID Numbers ICMJE	CB2011Chez
Has Data Monitoring Committee	Yes
Responsible Party	Michael Chez, MD, Sutter Health
Study Sponsor ICMJE	Sutter Health
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	Principal Investigator: | Michael Chez, MD | Sutter Health
Information Provided By	Sutter Health
Verification Date	August 2012

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**