



An Open-Label Trial Assessing Autologous
UMBILICAL CORD BLOOD
for Treatment of

YOUNG CHILDREN WITH AUTISM

An Open-Label Trial Assessing Autologous Umbilical Cord Blood for Treatment of Young Children with Autism

An Update

Excerpts For



Stem Cells Translational Medicine

Twenty-five 2- to 6-year-old children with ASD participated in this trial. Clinical outcome measures included the Vineland Adaptive Behavior Scales-II Socialization Subscale, Expressive One-Word Picture Vocabulary Test-4, and the Clinical Global Impression-Improvement Scale.

The trial was approved by the Duke Hospital Institutional Review Board and conducted under IND #15949. ClinicalTrials.gov identifier is NCT02176317.

Abstract

Participants

Autism spectrum disorder (ASD) is a heterogeneous neurodevelopmental disorder characterized by social communication deficits and the presence of restricted interests and repetitive behaviours.

Twenty-five 2- to 6-year-old children with ASD participated in this trial. Clinical outcome measures included the Vineland Adaptive Behavior Scales-II Socialization Subscale, Expressive One-Word Picture Vocabulary Test-4, and the Clinical Global Impression-Improvement Scale. Structural connectivity was measured at baseline and at 6 months in a subset of 19 children with 25-direction diffusion tensor imaging and deterministic tractography.

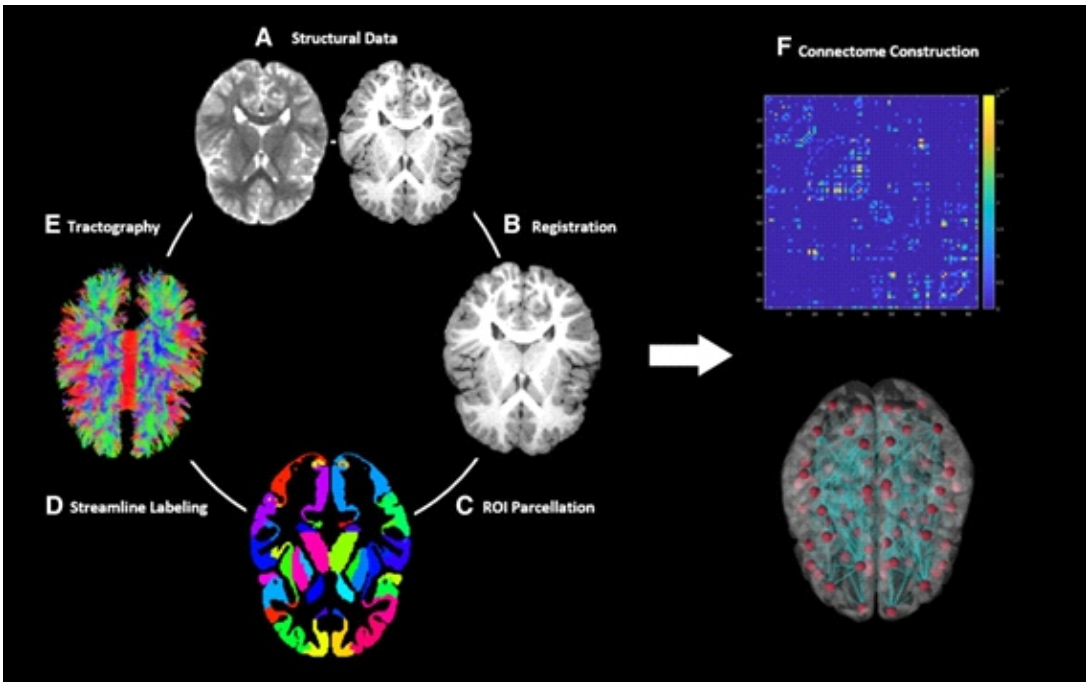
It is well established that individuals with ASD have different patterns of white matter development as compared to individuals with- out ASD. Specifically, studies following infant siblings at high risk for autism have provided evidence for altered global white matter structure by 6 months of age in those infants who later develop autism.

Study Design: The aims of the phase I trial were to evaluate safety of the treatment and to assess the feasibility and sensitivity to change of various primary and secondary outcome measures and biomarkers for use as end-points in a future phase II randomized, placebo-controlled clinical trial. This was a single-site study involving 25 participants with ASD. Children with a confirmed diagnosis of ASD and a banked autologous umbilical cord blood unit of adequate size and quality participated in the trial.

At their baseline visit, they were administered clinical evaluations and infusion of their cells. At 6 and 12 months post baseline, participants returned for follow-up clinical assessments. Additional caregiver interviews and questionnaires were collected at 3, 9, and 12 months post baseline.

Findings

Behavioral improvements were associated with increased white matter connectivity in frontal, temporal, and subcortical regions (hippocampus and basal ganglia) that have been previously shown to show anatomical, connectivity, and functional abnormalities in ASD. The current results suggest that improvements in social communication skills and a reduction in symptoms in children with ASD following treatment with autologous cord blood infusion were associated with increased structural connectivity in brain networks supporting social, communication, and language abilities.



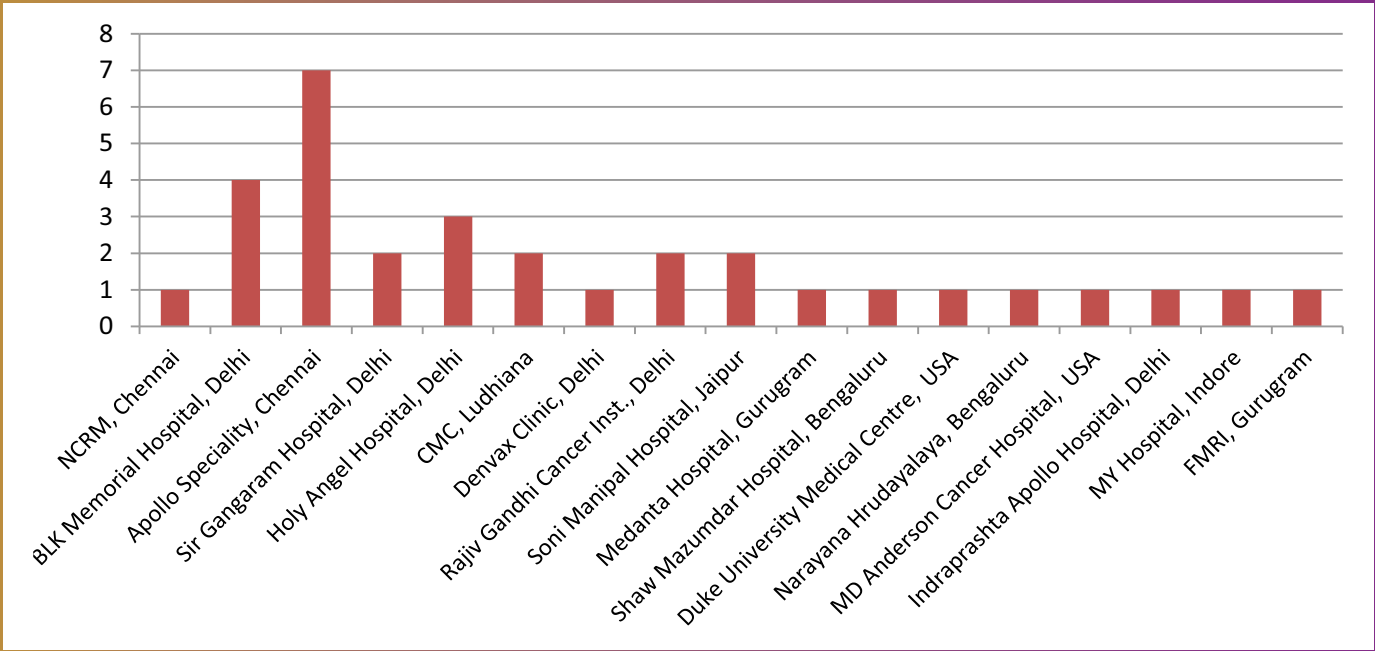
Overview of structural connectome creation. (A): Left, diffusion image; right, T1. (B) T1 registered in diffusion space. (C) Warp parcellated dilated UNC pediatric atlas to diffusion image space using advanced normalization tools. (D) Parcellated ROIs used to label tractography results. (E) DTI and deterministic tractography using the Connectome Mapper. (F) Visualization of connectome for a representative participant. Abbreviation: ROI, region of interest.

Discussion:

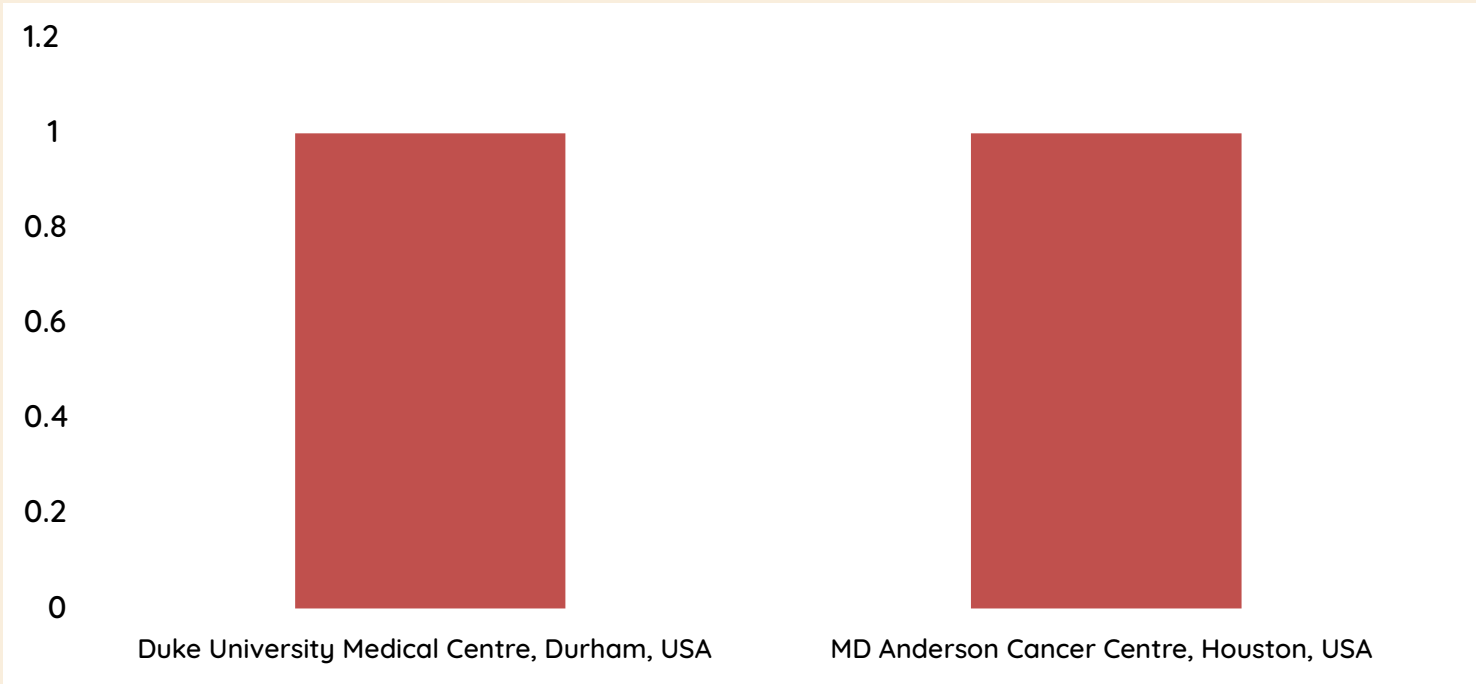
Previous published results showed improvements in social communication skills after a single infusion of autologous umbilical cord blood in young children with autism. The current study analyzed MRI biomarker outcomes and explored the hypothesis that the behavioral improvements were associated with concurrent changes in white matter connectivity in frontal, temporal, and specific subcortical regions (amygdala, hippocampus, and basal ganglia) that have been previously been shown to show anatomical, connectivity, and functional abnormalities in ASD.

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Reference: <https://cryoviva.in/Transplant-Outcomes>

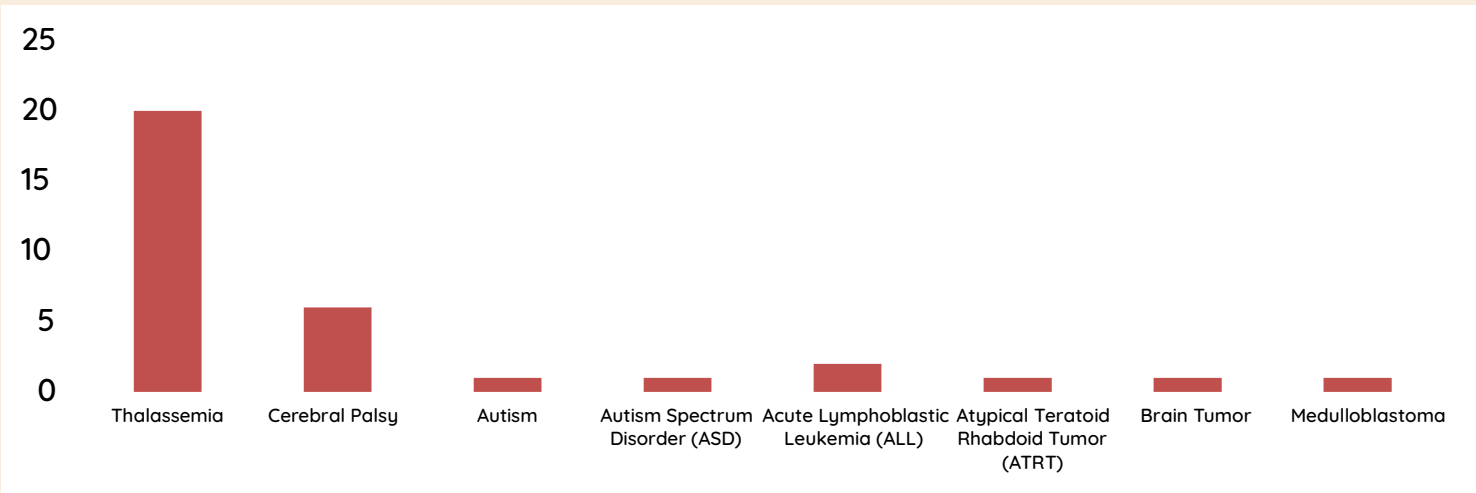


HEALTHCARE INSTITUTIONS FOR TREATMENTS
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CRYOVIVA INDIA CORD BLOOD PRODUCT (UCB-HSC) RELEASE TRACK RECORD

Number of Retrievals for Stem Cell Therapy



Get in touch to learn more:

T: + 91 8130 80 0211 | Toll Free: 1800 101 9587
Plot No. 19, Sector 35, Gurugram - 122004
Haryana, India

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to know more

