Study Participants & Setting: Thirty infants with brain lesions, but no ocular pathologies, have completed the follow up so far: 21 were born preterm (8 developed periventricular leukomalacia, 6 hydrocephalus, 7 intraventricular haemorrhage), 9 were born at term age (4 presented focal lesions, 3 diffuse white matter, 2 basal ganglia lesions).

Materials/Methods: Ten Italian Centers were involved in the development of a protocol for the assessment of visual function at neonatal age, at 6 and 12 months. Neonatal assessment included the evaluation of ocular motility, fixation, tracking, reaction to a colored target, discrimination of black/white stripes, attention at distance. This assessment, proposed by Ricci et al. in 2008, has already proved to be feasible in difficult settings, such as the Neonatal Intensive Care Unit. The 6 and 12 months assessment included the evaluation of ocular motility, fixation, tracking, saccadic movements, visual acuity (acuity cards technique), visual fields (kinetic perimetry), visual attention, attention at distance, contrast sensitivity (Hiding Heidy test) and stereopsis (Frisby Stereotest). This assessment takes 10–15 minutes. Training sessions have been organized in order to harmonize modality of assessment among the participating groups.

Results: Neonatal visual assessment identified a visual impairment in 6 infants (4 preterm and 2 term born). At 6 months 12 infants presented abnormal development of visual function; at 12 months the same infants still presented visual impairment. All the infants who presented a visual problem have been included in rehabilitation programs.

Conclusions/Significance: The protocol designed proved to be easy to use even by personnel not used to visual assessment. It was well accepted by infants and parents. At neonatal age it allowed to identify a visual problem when infants were still at the hospital and this made easier to support parents and help them to understand their baby’s special needs and abilities. This improved parent-child relationship. The increased number of infants with visual problems at 6 months could indicate the lack of development of the cortical areas responsible for the visual function. A larger cohort would be useful to better define relationship between site of lesion and impairment of specific visual aspects.

SP 61
Sibling umbilical cord blood infusion is safe in children with cerebral palsy
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Background and Objective(s): Preclinical and early phase clinical studies suggest that umbilical cord blood (CB) infusion has potential to help improve motor function in cerebral palsy (CP). As many children with CP do not have their own cord blood available, use of allogeneic cells is necessary to extend this potential therapy to all children who may benefit. We conducted a phase I, open label study of a single HLA-matched or partially-matched sibling CB infusion in children with CP to describe the safety of the procedure.

Study Design: Phase I, open label safety study.

Study Participants & Setting: Fifteen children (9 female, 5 male), ages 1-6, with spastic CP were enrolled and treated at an academic center. Children were eligible if they were (1) GMFCS level 2–4 or (2) GMFCS level 1 with hemiplegia if they used their affected hand as an assist only. Children with known genetic conditions, intractable seizures or severe microcephaly were ineligible. Sibling CB units had to have a precryopreservation total nucleated cell count (pTNCC) ≥2.5 × 10^7/kg, negative sterility cultures, negative maternal infectious disease screening and be a ≥4/8 HLA match with the participant.

Materials/Methods: Participants were evaluated at baseline and 6 months with functional evaluations (GMFM, Peabody), brain CT, and laboratory studies. On the day of infusion, sibling CB units were thawed and washed. After premedication with TYLENOL, BENADRYL and SOMONEDOL, participants received a dose of ≥2.5 × 10^7/kg cells, based on the pTNCC, intravenously over 5–10 minutes in the outpatient setting. Participants received IV fluids and were monitored for 1–2 hours post-infusion. Safety assessments were conducted 24 hours, 2 weeks, and 3, 6 and 12 months post-infusion.

Results: Fifteen children were enrolled with a median baseline age of 3.7 years (range 1.4–6). Sibling CB infusions had a median TNCC of 4.3 × 10^7/kg (range 1.8–5.2) and median CD3+ cell count of 0.6 × 10^7/kg (range 0.1–1.8). Four CB infusions were full HLA matches, 11 were haploidentical. All CB units had negative post-thaw sterility cultures. There were no acute infusion reactions and no unexpected imaging findings. No platelet antibodies, donor-specific HLA antibodies, or donor cells were detected in peripheral blood six months after infusion. With a median follow-up of 11 months, there were a total of 34 adverse events in 13 participants. Most (19/34) were attributed to common childhood infections, and none were related to the CB infusion. The only serious adverse event was unrelated to the infusion and occurred in a participant with a history of seizures who was hospitalized for a prolonged febrile seizure 5 months after CB infusion. Six months after infusion, participants improved a mean of 4.8 (SD 2.5) points on the GMFM-66 and 1 (SD 2.9) point on the Peabody Gross Motor Quotient.

Conclusions/Significance: Partially or fully-HLA matched sibling CB infusion is safe and feasible in young children with CP. Efficacy of allogeneic, partially matched CB infusion should be studied in a randomized trial.

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Validating risk assessments that determine vulnerability for choking and pneumonia in adults with intellectual and developmental disability
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Background and Objective(s): Choking and pneumonia, events associated with failures in airway protection during swallowing, are serious concerns for adults with intellectual and developmental disability (IDD). These events have non-fatal and