



Week 1: Clinical Trials and General Neonatology

Neonatal Clinical Trials I

Tuesday, June 9 4:30-6:00 pm EDT

Moderators

Ira Adams-Chapman
Annemarie Stroustrup

EDT	Abstract	Title	Presenting Author
4:30 pm		Introduction & General Information	
4:35 pm	3375446	Phase II Clinical Trial of Autologous Cord Blood Cells for Neonates with Hypoxic-Ischemic Encephalopathy	Michael Cotten
4:45 pm	3374554	A Randomized Trial of Laparotomy versus Peritoneal Drainage in Extremely Low Birth Weight Infants with Necrotizing Enterocolitis or Isolated Intestinal Perforation: Outcomes through 18-22 Months Corrected Age	Martin Blakely
4:55 pm	3342765	A randomized trial of higher versus lower hemoglobin transfusion thresholds for extremely low birth weight (ELBW) infants: The Transfusion of Prematures (TOP) Trial	Haresh Kirpalani
5:05 pm	3380521	Listen to your Mother: A randomized clinical trial of maternal speech exposure on structural brain connectivity in preterm newborns	Katherine Travis
5:15 pm	3376008	Magnetic Non-Invasive Auricular Acupuncture for Infant Comfort: A Multicenter Randomized Controlled Trial in Preterm Infants Requiring Eye-exam for Retinopathy of Prematurity (ROP)	Georg Schmolzer
5:25 pm	3374217	Early Higher Parenteral Lipid Intake Decreases Extra-Uterine Growth Restriction in Very Preterm Infants: A Randomized Controlled Trial	Wissam Alburaki
5:35 pm	3377315	Chlorhexidine Cord Care versus Dry Cord Care in Preterm Neonates less than 32 weeks gestation: An Open-label Randomized Controlled Trial	Shashi Dhir
5:45 pm		Wrap Up	

Question Asked	Answer Given	Answerer
Why did you choose CC over other tracts more closely associated with language function?	Several reasons - (1) corpus callosum is readily identified at these young ages (2) corpus callosum is implicated in language functions (primarily posterior regions) (3) we think that white matter pathways that may be sensitive to environment may not necessarily be the same pathways involved in a particular function	Katherine Travis
Was MD of frontal CC selected apriori as primary outcome?	MD was a priori metric we chose CC for the above mentioned reasons and because identified in all subjects	Katherine Travis
Congrats on your work!	Thank you!!	Katherine Travis
Is there a difference in rates of NEC?	NEC was an exclusion criteria so no babies had NEC in this sample	Katherine Travis
any effects of mothers with bilingual language background?	The sample was too small to examine this effects	Katherine Travis
since 40 to 50% of brain growth happens after 34 weeks, should we consider this treatment for LPIs?	absolutely, we chose <32 because of risk for white matter brain injuries, and neurodevelopmental delays is problematic for this group and also because <32 weeks automatically get brain imaging as part of routine care at our institution	Katherine Travis
Duration of intervention?	average was 2 weeks and had to have a minimum of 5 days before MRI	Katherine Travis
Why were <26 w were not included though they were most vulnerable?	<24 weeks were excluded mostly because of overlap with existing trials in our NICU, and unlikely to transition to intermediate care nursery where treatment was administered. Future studies should definitely explore this group given their risks.	Katherine Travis
are the NICUs shared in the study a single room per baby ?	this was open bay NICU, with several rooms, usually no more than one baby enrolled at a time	Katherine Travis
What was the incidence of NEC in the two arms?	NEC was an exclusion criteria so no babies had NEC in this sample	Katherine Travis
Were these groups any different in the incidences of IVH ?	no group differences in IVH	Katherine Travis
What exactly were the children hearing to ? parents singing or story readings?	parents reading a story (Chapter 1 from Paddington bear)	Katherine Travis
Does Repeated usage of MAA provide the same effectivity or does it decrease over time	Thanks, we do not know, in a previous study we used MAA in term infants for heel pricks and the magnets were left on the pain reduction.	Katherine Travis
maternal vs human voice significant?	relevant for future investigations - speech is relevant for language perception in older infants, needs to be explored at these younger ages	Katherine Travis
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Does Repeated usage of MAA provide the same effectivity or does it decrease over time	Thanks, we do not know, in a previous study we used MAA in term infants for heel pricks and the magnets were left on the pain reduction.	Georg Schmolzer

