Studying intranasal human milk as stem cell therapy in preterm infants with intraventricular hemorrhage

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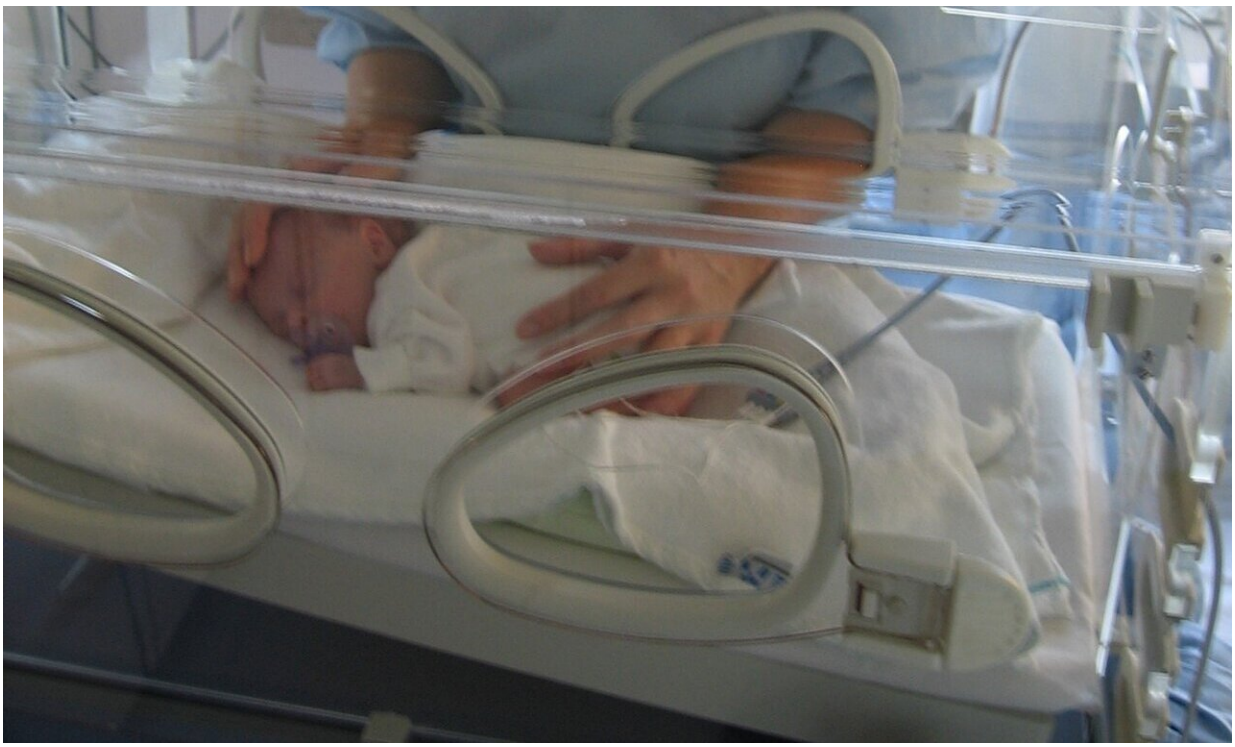

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A new study demonstrates that intranasal human milk is a safe and feasible intervention for intraventricular hemorrhage, a serious cause of morbidity in preterm infants. Findings from the study will be presented

during the Pediatric Academic Societies (PAS) 2022 Meeting, taking place April 21-25 in Denver. This is the first prospective trial on safety and feasibility of intranasal human milk administration in neonates with intraventricular hemorrhage.

Intraventricular hemorrhage is a common cause of brain injury with potential resultant neurodevelopmental sequalae for preterm infants. Stem cell therapies are being developed as a novel brain injury treatment. Fresh human milk contains pluripotent stem cells that produce neuronal cells in vitro. Animal models of neonatal brain injury have found milk stem cells in brain tissue of suckling mice with neuroprotective effects. Nasal vascularity and the permeable neonatal blood brain barrier potentially allow stem cell delivery to brain tissue via fresh intranasal human milk administration.

"Our study, 'Intranasal Human Milk as Stem Cell Therapy in Preterm Infants with Intraventricular Hemorrhage: Safety, Feasibility and Short-Term Outcomes,' attempts to harness the power of fresh human milk, which has stem cells and growth factors, as an intervention for very preterm babies with brain bleeds, a condition currently with no effective therapy," said Alessia Gallipoli, MD, neonatal-perinatal medicine fellow at the University of Toronto. "Our prospective trial in Toronto, the first in the world, showed that these preterm infants were able to tolerate nasal milk therapy through 28 days of life without major safety events. We hope to use this preliminary data to plan a larger trial to gain more information on the effect of intranasal breastmilk on short- and long-term outcomes for this patient population."

N=37		Median [IQR] or n (%)
Infant Gestational Age at Birth (weeks)		27.7 [25.4, 29.1]
Infant Birth Weight (grams)		1000 [750, 1215]
Male Infant		19 (51.4%)
Worst grade of IVH	Grade 1	17 (45.9%)
	Grade 2	7 (18.9%)
	Grade 3	1 (2.7%)
	Grade 4	10 (27.0%)
Received goal 2 aliquots IHM 2x/day (vs 1x/day)		27 (73.0%)
Received goal IHM dose of 0.4mL/aliquot		29 (78.4%)
Total days of IHM received		17 [9, 20]

Patient Characteristics and IHM Dosing Information IVH: Intraventricular hemorrhage; IHM: intranasal human milk. Credit: University of Toronto Temerty Faculty of Medicine

N=162 surveys		n (%)
Clinical position	Registered nurse	137 (85)
	Registered respiratory therapist	19 (12)
	Nurse practitioner	2 (1)
	Medical doctor	3 (2)
Years of experience in role (n=135)	0-2 years	39 (29)
	3-5 years	23 (17)
	6-10 years	21 (16)
	11-15 years	22 (16)
	15+ years	30 (22)
Did you administer the intranasal HM dose? ("yes")[1]		137 (85)
Were the parents involved in the administration of the dose? ("yes")[1]		66 (41)
Dose was given at same time as other planned clinical care ("yes")[1]		146 (90)
It was easy to time the intranasal milk dose to give with clinical care ("strongly agree/agree")[2]		137 (85)
Giving 2 aliquots within a few minutes of each other was feasible for clinical workflow ("strongly agree/agree")[2]		119 (73)
Giving these doses twice in 24 hours is/would be feasible ("strongly agree/agree")[2]		132 (81)
Giving/observing the intranasal milk administration is stressful for me ("strongly agree/agree")[2]		45 (28)
Receiving the milk dose was stressful for the baby ("strongly agree/agree")[2]		37 (23)
I had enough information about the study to feel comfortable giving the dose ("strongly agree/agree")[2]		138 (85)
I think that clinical trials are important to do in our NICU ("strongly agree/agree")[2]		150 (93)
I think it's ok to involved bedside staff in clinical trials in our NICU ("strongly agree/agree")[2]		149 (92)
I think it's a good idea to involve parents in giving the intervention ("strongly agree/agree")[2]		119 (73)

Clinical Provider Survey Results HM: human milk; NICU: neonatal intensive care unit; (1) survey answer options: yes/no; (2) survey answer options: strongly agree/agree/neutral/disagree/strongly disagree. Credit: University of Toronto Temerty Faculty of Medicine

Short-term outcomes are currently being compared to a historical

control. Next steps will explore long-term neurodevelopmental outcomes at 18 months to plan for larger multicenter trials.

More information: Conference: www.pas-meeting.org/

Provided by American Pediatric Society

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