



National Pediatric Cardiology  
Quality Improvement Collaborative

## Research Explained

---

### **A Randomized Trial of an Exclusive Human Milk Diet in Neonates with Single Ventricle Physiology**

Blanco C, Hair A, Justice LB, Roddy D, Bonagurio K, Williams PK, Machado D, Marino BS, Chi A, Takao C, Gordon E, Ashrafi A, Cacho N, Pruetz JD, Costello JM, Cooper DS, for the Cardiac Neonate Nutrition Study Group. J Pediatr 2023. doi: 10.1016/j.peds.2022.11.043. PMID: 36528055

---

Sinai C. Zbylewski (physician) and Richard James (parent)

### ABOUT THIS STUDY

#### **Why is this study important?**

---

- Good nutrition helps with good outcomes for infants and children undergoing heart surgery.
- Infants with single ventricle physiology have difficulty growing.
- Infants with single ventricle physiology are more likely to have feeding problems and serious complications such as necrotizing enterocolitis (NEC), a disease of the intestines.
- There is a lot of research about feeding infants with complex heart disease, but we are still not sure about the best way to do this after heart surgery.
- This study shows that infants with single ventricle physiology grow better and are less likely to get NEC when they are fed with only human milk (breast milk) after their first surgery.

#### **What is the goal of the study?**

---

- To find out if weight gain and other clinical outcomes improve in infants with single ventricle physiology who are fed only human milk compared with infants who are fed human milk and formula.

#### **How was this study performed?**

---

- Parents of newborn infants with single ventricle physiology about to have their first surgery were asked to enroll their child in the study. Families from 10 different centers enrolled.
- Premature infants and newborn infants with serious medical complications at birth were not included in the study.

- Infants were randomly placed in either the intervention group or the control group.
  - The intervention group received human milk and human milk-based fortifier after heart surgery.
    - The human milk was from the mother or from a donor if mother's milk was not available.
  - The control group received a combination of human milk and formula after heart surgery.
- The medical teams did not know if the infant was in the intervention group or the control group, so that they would not treat them differently in any way.
- All the infants in the study were fed according to a standardized plan
- The intervention and control groups were compared to see if they had differences in outcomes.
  - The main outcomes studied were how quickly the infant gained weight (velocity) and how the infant's weight compared to other infants of the same age and sex (z-score).
  - The other outcomes studied were growth rates of length and head circumference, feeding intolerance, feeding interruptions, length of hospital stay, and hospital complications.

#### **What were the results of the studies?**

---

- 107 infants from 10 centers were included in the study.
- Infants who were fed only human milk had the following results compared to infants who received both human milk and formula:
  - Faster rate of growth (~8 more grams/day)
  - More likely to be able to be fed higher calorie feeds
  - Increased protein intake
  - Decreased risk of NEC
- There were no differences between the intervention and control groups in rates of feeding intolerance.

#### **What are the limitations of the study?**

---

- This study followed infants for only 30 days after feeds were started after heart surgery so the long-term effects are unknown.
- The feeding plan for infants only receiving human milk got more calories more quickly than the other group, which may have affected the results.
- The study was not designed to find out if the human milk-based fortifier itself decreased the incidence of NEC.
- Scales used to weigh infants were not standardized at the study centers
- There may have been other factors not accounted for in the research design that may have affected the results of the study.

#### **What it all means**

---

- After their first surgery, infants with single ventricle physiology have faster growth and are less likely to contract NEC if they are fed only on human milk.

- Further research is needed to find out if there are prolonged benefits and improved outcomes past the immediate postoperative period.