

BOND: Direct Breastfeeding to Enhance Maternal and Infant Health in Congenital Heart Disease

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 18 years and over

Healthy Volunteers: This study is NOT accepting healthy volunteers

Both mothers and infants are study participants.

Inclusion criteria:

1. Pregnant individual carrying a fetus diagnosed with CHD or biological mother of an infant diagnosed with CHD in the neonatal period.
2. Fetus or newborn with CHD anticipated to require cardiac surgery or transcatheter intervention in the first 30 days of life.
3. Admission to the ICU (either CICU or NICU) at participating center in 1st week of life and for whom cardiac surgical or transcatheter intervention is anticipated in the first 30 days of life.
4. Willing to comply with protocol and provide written informed consent

Exclusion Criteria:

1. Mother, fetal, or infant medical condition determined by a treating clinician to be contraindicated to study participation.
2. Mother with a severe, untreated psychiatric condition, substance use disorder, or other circumstances that, in the opinion of the investigator, would interfere with engagement with study tasks or safe participation in the trial.
3. Mother with a moderate to severe intellectual disability or is otherwise unable to provide informed consent.
4. Infant birthweight <3rd percentile for gestational age
5. Infant gestational age < 36 weeks
6. Infant with known genetic disorder likely to impact breastfeeding, such as trisomy 21 or cleft palate
7. Medical condition or congenital anomaly that precludes safe direct breastfeeding for the infant as determined by investigator

Conditions & Interventions

Interventions:

OTHER: Breastfeeding clinical practice guideline (CPG) for congenital heart disease (CHD)

Conditions:

Congenital Heart Disease (CHD)

Keywords:

Direct breastfeeding, CHD, Infant neurodevelopment, Maternal Mental Health

More Information

Description:

The primary objective of this study is to enhance the rates of direct breast feeding (DBF) among infants with congenital heart disease (CHD), and to gain insights into the implications of DBF on key metrics of child and parent well-being. A multicenter parallel cluster platform design will be employed. The intervention will be a multifaceted approach to enhance direct breastfeeding. Participating sites will be randomized into either intervention (strategies to enhance direct breastfeeding) or conventional care.

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Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT07582848

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