

Cord Clamping Among Neonates With Congenital Heart Disease

NCT06153459

Status	RECRUITING
Phase	Not Applicable
Sponsor	Carl Backes, MD
Enrollment	500 participants

Key Eligibility Criteria

Inclusion (7)

- Fetal diagnosis of congenital heart disease (CHD) by prenatal ultrasound / echocardiography from local fetal ECHO, conducted on or after 18 weeks of gestation and prior to randomization. The study fetal diagnosis of CHD must be rated as 3 - 6 on the Fetal Cardiovascular Disease Severity Score (FCDSS), as determined by independent evaluators at the CORD-CHD trial ECHO Core at the Children's Hospital of Philadelphia (to determine final FCDSS eligibility for randomization).
- For each potential participant that has provided consent, the most relevant diagnostic prenatal ultrasound will be uploaded (shared) between 32 weeks of gestation and randomization for review by the ECHO Core. The ECHO Core will make the final FCDSS determination for eligibility status and stratification assignment.}]
- \[NOTE: A fetal diagnosis of CHD rated as 3 - 6 FCDSS per local review, including borderline cases, will be used to determine preliminary eligibility for consent. Among borderline cases, eligible patients will be included if there is a reasonable expectation of the need for surgery or cardiac catheterization during the birth hospitalization.\]
- Singleton gestation.
- Gestational age at randomization for impending deliveries between 37 0/7 - 41 6/7 weeks of gestation inclusive based on clinical information and evaluation of the earliest ultrasound determined using criteria proposed by the American Congress of Obstetricians and Gynecologists (ACOG), the American Institute of Ultrasound in Medicine and the Society for Maternal-Fetal Medicine.

... and 2 more (see full listing online)

Exclusion (13)

- Pregnant individual is a gestational carrier or surrogate.
- Compromise of the pregnant individual (e.g., vasa previa, placental accreta with hypotension, placental abruption, amniotic fluid embolism, uterine rupture, uterine inversion, disseminated intravascular coagulation), as determined by local care team
- \[NOTE: There is no limitation on pregnant individual's age\]
- Fetal demise or planned termination of pregnancy prior to randomization
- Tachyarrhythmia requiring transplacental therapy

... and 8 more (see full listing online)

Locations (21 total)

Children's of Alabama, Birmingham, Alabama, United States
Cedars-Sinai Medical Center, Los Angeles, California, United States
Children's Hospital of Orange County, Orange, California, United States
... and 18 more locations

<https://clinicaltrials.gov/study/NCT06153459>

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