Trial of FETO for Severe Congenital Diaphragmatic Hernia

NCT05450653

Status	RECRUITING
Phase	Not Applicable
Sponsor	Aimen F. Shaaban, MD
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (12)

- Provision of signed and dated informed consent form
- Pregnant individuals age 18 years and older
- Singleton pregnancy
- No pathogenic variants on prenatal chromosomal microarray or pathologic findings on karyotype analysis. Results by fluorescence in situ hybridization (FISH) will be acceptable if the patient is \> 26 weeks
- Isolated left CDH with severe pulmonary hypoplasia with o/e LHR \</=25% with liver up (measured at 18 weeks 0 days to 29 weeks 5 days of gestation) OR Isolated right CDH with severe pulmonary hypoplasia with o/e LHR \</=35% with liver up (measured at 18 weeks 0 days to 29 weeks 5 days of gestation)

... and 7 more (see full listing online)

Exclusion (12)

- Rubber latex allergy
- Presence of chromosomal abnormalities or anatomic anomalies that are known to significantly alter survival prognosis (i.e., CDH and congenital heart disease). No cases will be removed post hoc if abnormalities are discovered during post-operative monitoring
- History of preterm labor, cervix shortened to d20 mm at enrollment or at 24 hours prior to FETO balloon insertion procedure) or uterine anomaly strongly predisposing to preterm labor or placenta previa
- Maternal contraindication to fetoscopic surgery or severe maternal medical condition in pregnancy
- History of incompetent cervix with or without cerclage

... and 7 more (see full listing online)

Locations (1 total)

Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois, United States