Safety and Efficacy of FETO in CDH Phase III

Status: RECRUITING

Eligibility Criteria

Sex: FEMALE
Age: 18 years to 50 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria:

- Pregnant women 18 years and older, who are able to consent
- Singleton pregnancy
- Gestational age at enrollment is prior to 296 weeks
- Intrathoracic liver herniation
- Isolated Left CDH with o/e LHR < 30% at enrollment (180 to 295 weeks) or
- Isolated Right CDH with o/e LHR < 45% at enrollment (180 to 295 weeks)
- Normal fetal karyotype with confirmation by culture results, CMA with non-pathological variants, WES or WGS. Results by fluorescence in situ hybridization (FISH) will be acceptable if the patient is > 26 weeks
- Cervical length by transvaginal ultrasound > 20 mm within 24 hours prior to FETO procedure
- Patient meets psychosocial criteria
- Informed consent understood

Exclusion Criteria

- Patient < 18 years of age
- Multi-fetal pregnancy
- History of natural rubber latex allergy
- Preterm labor, cervix shortened (< 20 mm at enrollment or within 24 hours prior to FETO balloon insertion) or uterine anomaly strongly predisposing to preterm labor, or placenta previa.
- Psychosocial ineligibility, precluding consent:
    - Inability to reside within 30 minutes of Cincinnati Children's Hospital Medical Center and inability to comply with the travel for the follow-up requirements of the trial.
    - The patient does not have a support person (e.g. spouse, partner, mother) available to stay with the patient for the duration of the pregnancy at Cincinnati Children's Hospital Medical Center.
- Bilateral CDH, isolated LCDH with o/e LHR ≥ 30%, isolated RCDH with o/e LHR > 45%, as determined by ultrasound.
- No liver herniation into thoracic cavity
- Additional fetal anomaly and chromosomal abnormalities, associated anomalies recognized to alter survival prognosis (i.e., congenital heart disease) or presence of an underlying genetic syndrome (i.e., Fryns) by ultrasound, MRI, or echocardiogram at the fetal treatment center.
- Maternal contraindication to fetoscopic surgery or severe maternal medical condition in pregnancy
- History of incompetent cervix with or without cerclage
- Placental abnormalities (previa, abruption, accreta) known at time of enrollment
- Maternal-fetal Rh isoimmunization, Kell sensitization or neonatal alloimmune thrombocytopenia affecting the current pregnancy
- Maternal HIV, Hepatitis-B, Hepatitis-C positive because of the increased risk of transmission to the fetus during maternal-fetal surgery. If the patient's HIV status is unknown, the patient must be tested and found to have negative results before enrollment.
- Positive Hepatitis B surface antigen or presence of Hepatitis C in maternal blood uterine anomaly such as Mullerian duct abnormality, large or multiple fibroids that prohibit safe fetoscopic procedure
- There is no safe or technically feasible fetoscopic approach to balloon placement
- Participation in another intervention study that influences maternal and fetal morbidity and mortality, or participation in this trial in a previous pregnancy

Conditions & Interventions

Interventions:
DEVICE: FETO, Fetal Endoluminal Tracheal Occlusion
Conditions:
Congenital Diaphragmatic Hernia, Pulmonary Hypoplasia, Pulmonary Hypertension

More Information

Description:

Tracheal occlusion IDE approved by FDA for congenital diaphragmatic hernia fetuses and standard of care control group

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