

Feto-Endoscopic Tracheal Occlusion (FETO) for Severe Congenital Diaphragmatic Hernia

Status: RECRUITING

Eligibility Criteria

Sex: FEMALE

Age: 18 years to 50 years old

Healthy Volunteers: This study is also accepting healthy volunteers

Inclusion Criteria:

- Isolated CDH with liver up
- Severe pulmonary hypoplasia with ultrasound O/E LHR <25% at the time of surgery
- Gestational age at FETO procedure 27 weeks 0 days to 29 weeks 6 days
- Moderate pulmonary hypoplasia with ultrasound O/E LHR <30% and liver-up at the time of surgery
- Gestational age at FETO procedure 30 weeks 0 days to 31 weeks 6 days in this moderate category
- Maternal age greater than or equal to 18 years
- Gestational age at enrollment prior to 29 weeks 6 days, or 31 weeks 6 days in moderate category
- Normal karyotype or FISH
- Normal fetal echocardiogram
- Singleton pregnancy
- Willing to remain in the greater Cincinnati area for remainder of pregnancy
- Family considered and decline option of termination of the pregnancy at less than 24 weeks 0 days
- Family meets psychosocial criteria

Exclusion Criteria:

- Patient < 18 years old
- Multi-fetal pregnancy
- Rubber latex allergy
- Preterm labor, cervix shortened (<15 mm) or uterine anomaly strongly predisposing to preterm labor, placenta previa
- Bilateral CDH, isolated left sided CDH with an O/E > 30%
- Additional fetal anomaly by ultrasound, MRI, or echocardiogram
- Chromosomal abnormalities
- Maternal contraindications to fetoscopic surgery or severe maternal condition in pregnancy
- Incompetent cervix with or without a cerclage
- Placental abnormalities known at time of enrollment
- Maternal HIV, Hepatitis B, Hepatitis C
- Maternal uterine anomaly
- 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: Fetal Tracheal Occlusion

Conditions:

Congenital Diaphragmatic Hernia, Pulmonary Hypoplasia, Pulmonary, Hypertension

More Information

Description:

Tracheal occlusion IDE approved by FDA for congenital diaphragmatic hernia fetuses.

Contact(s): Sandi Bechtol - sanda.bechtolt@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT02986087

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